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Supreme Court, U.S.
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JOSEPH F. SPANIOL, JR.
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No. ———

IN THE
Supreme Court of the United States
OCTOBER TERM, 1987

PLAYTEX HOLDINGS, INC.,
Petitioner,
v.
KELLY M. O'GILVIE, *et al.*,
Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

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QUESTIONS PRESENTED

1. Whether, in light of this Court's statement last Term in *Tull* v. *United States* that "[n]othing in the [Seventh] Amendment's language suggests that the right to a jury trial extends to the remedy phase of a civil trial," a district court in a diversity case may independently reduce a jury's punitive damage award, though not the accompanying compensatory award, in light of the defendant's post-verdict reform.

2. Whether the District Court's award against petitioner of $10 million in punitive damages on a products liability verdict of $1.53 million in compensatory damages violated the Excessive Fines Clause of the Eighth Amendment, or was otherwise invalid under the Due Process Clause of the Fifth Amendment, because it was vastly out of proportion to the penalty prescribed by Congress for analogous conduct.*

3. Whether 21 U.S.C. § 360k and its implementing rule, 21 C.F.R. § 808.1, which expressly preempts "any [state] requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation or court decision), which is different from or in addition to any requirement" imposed by federal law, preempt state-law tort suits against tampon manufacturers when those suits are premised on the theory that the product's warnings, though complying with the specific requirements imposed by the FDA, were nevertheless inadequate.

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* A similar question is already before the Court in *Bankers Life & Casualty Co.* v. *Crenshaw*, No. 85-1765 (prob. juris. noted March 10, 1987).

PARTIES TO THE PROCEEDING

Petitioner, Playtex Holdings, Inc.,** is the corporate successor to International Playtex, Inc., which was the defendant in the district court and appellee/cross-appellant in the court of appeals. Respondents are Kelly M. O'Gilvie, individually, as administrator of the estate of Betty L. O'Gilvie, and as representative for his children, Stephanie L. O'Gilvie and Kevin M. O'Gilvie.

** Pursuant to Rule 28.1, petitioner states that it has no parent or affiliate corporations, or domestic subsidiary corporations other than wholly-owned subsidiaries.

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

Playtex Holdings, Inc., petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Tenth Circuit.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a) is reported at 821 F.2d 1438. The opinion of the district court (Pet. App. 37a) is reported at 609 F. Supp. 817.

JURISDICTION

The opinion of the court of appeals affirming in part and reversing in part the district court's order of remittitur was entered on June 18, 1987. A timely petition for rehearing, with suggestion for rehearing *en banc*, was denied on September 24, 1987. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1) (1982).

CONSTITUTIONAL, STATUTORY AND REGULATORY PROVISIONS INVOLVED

Article VI, clause 2 of the Constitution provides:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby; any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

The Fifth Amendment provides:

> No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of war or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

The Seventh Amendment provides:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.

The Eighth Amendment provides:

> Excessive Bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted.

21 U.S.C. § 360k (1982), 21 C.F.R. § 801.430 (1987), and 21 C.F.R. § 808.1 (1987) are set forth at Pet. App. 65a-72a.

STATEMENT OF THE CASE

This is a products liability action tried, purusant to diversity jurisdiction, in federal district court. Respondents are Kelly O'Gilvie, as an individual, as administrator of the estate of his deceased wife, and as representative of his minor children. Respondents alleged that tampons manufactured by petitioner's corporate predecessor, International Playtex, Inc. ("Playtex"), caused Mrs. O'Gilvie's death, due to toxic shock syndrome, in 1983. Respondents set forth various theories of liability, all bottomed on the notion that the warning statements included on and in petitioner's packaging pursuant to regulations issued by the U.S. Food and Drug Administration ("FDA") were inadequate.[1] Respondents also sought punitive damages, solely on the theory that the allegedly inadequate warning demonstrated "reckless disregard" for human life.[2] The jury found for respondents: it awarded them $1,525,000 in actual damages and $10 million in punitive damages.[3]

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[1] The verdict form permitted the jury to find for plaintiffs only if the jury answered "yes" to the following question: "Did the label and instructions inside and outside the Playtex box at the time the product was being used by Betty O'Gilvie adequately and fairly inform and warn Betty O'Gilvie of the risk of TSS which may be fatal from using Playtex tampons?" (Pet. App. 50a).

[2] The verdict form permitted an award of punitive damages only as follows:

* * * *

"9. Was the failure of International Playtex to adequately warn about the increased risk of toxic shock syndrome with usage of Playtex super-deoderant tampons a reckless disregard by International Playtex of the consequences of its acts?

Yes —— No. ——

"10. If your answer to No. 9 is 'yes', you may assess punitive damages as you feel are warranted from the evidence.

Punitive damages $ ——————"

(Pet. App. 51a).

[3] Pursuant to Kansas law, the jury found Mrs. O'Gilvie's treating physician, who was not a party to the action, 20% at fault and

The district court denied petitioner's motion for remittitur. It found that the punitive damage award was not excessive, and did not shock the judicial conscience. (Pet. App. 59a-62a). Nevertheless, at that same hearing, the court stated that it would reduce or eliminate the punitive damage award if Playtex removed its product from the market. (Pet. App. 40a; 62a). Playtex did, and the court subsequently reduced the punitive damage award to $1,350,000. In so doing, the court did not offer respondents a new trial.

Although the court referred to its order as one of "remittitur," it is clear that it was not simply a procedurally defective invocation of Fed. R. Civ. P. 59. Rather, the district court was being creative. In making its offer, it analogized the imposition of punitive damages to criminal sentencing:

> "I see the jury's verdict as quasi-criminal. . . . As such, when I have people before me for punishment, mitigation is of interest to me. When somebody says: I was wrong, I'm ready to change, I'm ready to do what's right, [that] makes all the difference in the world." (Pet. App. 62a).

Respondents appealed from the order, and Playtex cross-appealed from the judgment itself. In the court of appeals, Playtex pointed out that the punitive award greatly exceeded the maximum federal fine for any relevant offense. (Indeed, the maximum federal penalty for conduct analogous to that alleged was $10,000 for mislabeling with intent to defraud or mislead. *See* 21 U.S.C. § 333(b)(1982). Accordingly, petitioner argued, "[t]o allow judgment greater than the maximum criminal award without the more stringent standard of proof applicable to a criminal action will result in a seizure of

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Playtex 80% at fault. The judgment entered against Playtex for compensatory damages was therefore for 80% of the compensatory award (but 100% of the punitive award).

Playtex'[s] property without due process of law." (Brief of Defendant-Appellee, Cross-Appellant at 43; *see also id.*, at 42-43, 49-50.) [4] Petitioner also argued that the trial court had properly reduced the punitive damage award, and, in so doing, had properly considered petitioner's post-verdict behavior. (*Id.* 43-49.) [5]

On June 18, 1987, a panel of the court of appeals (Judge Seth, dissenting) affirmed the judgment and reversed the order of remittitur. The majority brushed aside Playtex's argument that the punitive damage award was excessive when measured against comparable criminal penalties. The court apparently considered it to be among the "remaining arguments," which it thought were "without merit." (Pet. App. 23a).

The majority concluded that "the trial court lacked the power to order a remittitur based on post-trial occurrences." (Pet. App. 19a).[6] That was so, the court explained, because "absent an award so excessive as to shock the judicial conscience and to raise an irresistible inference that passion, prejudice, corruption or other improper cause invaded the trial, the jury's determination of the damages is considered inviolate." (Pet. App. 20a, *quoting Malandris v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 703 F.2d 1152, 1168 (10th Cir. 1981) (en banc) (plurality opinion) (emphasis omitted), *cert. de-*

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[4] Petitioner advanced the same argument in the district court. *See* Motion of Defendant International Playtex, Inc. for Judgment Notwithstanding the Verdict and New Trial, at 10-11.

[5] Petitioner did not, however, argue the substance of the third question presented here—that 21 U.S.C. § 360k, 21 C.F.R. § 808.1 and 21 C.F.R. § 801.430 together preempt the state-law cause of action asserted in the district court. *But see* n.23, *infra.*

[6] The court found that the district court's failure to offer respondents the option of a new trial made its remittitur order appealable. (Pet. App. 17a). *See, Donovan* v. *Penn Shipping Co.*, 429 U.S. 648, 650 (1977) (per curiam). Otherwise, the court did not focus on that aspect of the case.

nied, 464 U.S. 824 (1983)). Because *post*-trial occurrences obviously are irrelevant to whether the *trial* was sound, the court thought they therefore must also be irrelevant to the determination of an appropriate punitive award. Accordingly, the court held that the district court erred "because it expressly found that the award did not shock its judicial conscience and because it based its decision to remit on events occurring after trial." (Pet. App. 20a) (footnote and emphasis omitted).[7]

Playtex filed a timely petition for rehearing and suggestion for rehearing *en banc*. The panel denied the petition on September 24, 1987. With Judges Moore, Tacha and Baldock dissenting without opinion, the full court also rejected Playtex's suggestion for rehearing *en banc*. (Pet. App. 44a).

REASONS FOR GRANTING THE WRIT

1. Whether A Federal Court May Reduce An Award Of Punitive Damages, By Itself, And Based Upon Post-Trial Occurrences, Is An Important Question Left Open By This Court's Prior Decisions.

The Seventh Amendment provides: "In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law." The second clause of that Amendment has long been held to preclude a federal judge from unilaterally reducing the amount of *compensatory* damages a jury has awarded, without offering the successful plaintiff the option of a new trial. *Kennon* v. *Gilmer*, 131 U.S. 22, 28-30 (1889).[8] How-

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[7] The court likewise noted that its reasoning was in accord with the substantive law of Kansas. (*See* Pet. App. 21a).

[8] *See also Dimick* v. *Schiedt*, 293 U.S. 474 (1935) (additur not permitted in trial governed by Seventh Amendment). In dissent,

ever, this Court has never had occasion to consider whether *Kennon*'s reasoning also applies to *punitive* damages.[9] Indeed, the Court recently suggested otherwise:

> "Nothing in the [Seventh] Amendment's language suggests that the right to a jury trial extends to the remedy phase of a civil trial. Instead, the language defines the kind of cases for which jury trial is preserved, namely 'suits at common law'. . . . We have been presented with no evidence that the framers meant to extend the right to a jury to the remedy phase of a civil trial."

Tull v. *United States*, 107 S. Ct. 1831, 1840 n.9 (1987) (citation omitted). Thus, in *Tull*, the Court held that the Seventh Amendment requires only that a jury determine *whether* a defendant would be liable for a civil penalty under the Clean Water Act. It does not require that the jury fix the *amount* of the penalty, which now may be set by the trial court. 107 S.Ct. at 1840.

Tull casts substantial doubt on *Kennon*'s application to punitive damage awards. If there is no Seventh Amendment right to have a jury determine the amount of punitive awards, there should be no Seventh Amendment objection to re-determination by the court after a verdict returned by a jury. The jury, in effect, would be advisory. *Cf.* Fed. R. Civ. P. 39(c).[10]

Justice Stone, joined by Hughes, C.J., and Brandeis and Cardozo, J.J., would have upheld the power of a federal district judge to impose, in the alternative, an additur or a new trial.

[9] The Seventh Circuit and the Supreme Court of Kansas have each assumed, without analysis, that *Kennon* does apply to punitive awards. *See, McKinnon* v. *City of Berwyn*, 750 F.2d 1383, 1391-92 (7th Cir. 1984); *Ford* v. *Guarantee Abstract & Title Co.*, 220 Kan. 244, 553 P.2d 254, 277-78 (1976).

[10] Even prior to *Tull*, *Kennon* was not read as barring courts from unilaterally altering awards of even compensatory damages,

The implications of *Tull* for tort reform—judicial and legislative—is an urgent matter that merits this Court's attention. The need for tighter judicial control over punitive awards is readily apparent. For example, "the number of punitive damage awards in Cook County grew from 3 in 1960-64 to 75 in 1980-84, and in San Francisco grew from 14 in 1960-64 to 51 in 1980-84. In San Francisco, almost one out of every seven plaintiffs' verdicts (13.6%) in the 1980-84 period included a punitive damage award." Tort Policy Working Group, *An Update on the Liability Crisis*, 48-49 (U.S. Dept. of Justice 1987) (footnotes omitted). At the same time, in Cook County "the average personal injury punitive damage award grew [in inflation-adjusted dollars, *id.* at 47 n.54] from $28,000 in 1970-74 to $1,934,000 in 1980-84, a 6,900% increase." *Id.* at 49 n.62 (citation omitted). Thus, the Task Force on Litigation Issues of the American College of Trial Lawyers observes:

> "one of the greatest problems with the current tort system is the way in which punitive damages are handled. Awards often bear no relationship to deterrence and reflect a jury's dissatisfaction with a defendant and a desire to punish, often without regard to the true harm threatened by a defendant's conduct. There is a general feeling that punitive damage awards should be more difficult to obtain

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where doing so would not require re-examining facts found by the jury. Thus, where the jury's award exceeds a statutorily-set amount of damages, it may summarily be reduced. *See SunRay Oil Corp.* v. *Allbritton*, 187 F.2d 475, 477 (5th Cir.), *cert. denied*, 342 U.S. 828 (1951); *Hartford Accident & Indemnity Co.* v. *Murphy*, 158 F.2d 506 (5th Cir. 1946) (jury award of 275 weeks of workmen's compensation reduced to 240, because remaining 35 weeks already paid). Likewise, in a contract case an award may be cut if it exceeds the only amount available as a matter of law. *See Garfield Aniline Works* v. *Zendie*, 43 F.2d 537, 538 (3d Cir. 1930) ("[u]nder the evidence, the plaintiff was entitled to $8,448.16 with interest, if he was entitled to anything. The verdict of the jury was clearly excessive, and it was a matter of simple mathematical calculation to determine the amount").

> and that the amounts of such awards should be controlled much more than they are at the present time. . . ."

American College of Trial Lawyers, *Report of the Task Force on Litigation Issues* 4 (1986). This Court, itself, has remarked that "juries assess punitive damages in wholly unpredictable amounts bearing no necessary relation to the actual harm caused," *Gertz* v. *Robert Welsh, Inc.*, 418 U.S. 323, 350 (1974); *see also, Smith* v. *Wade*, 461 U.S. 30, 59 (1983) (Rehnquist, J., dissenting) ("punitive damages are frequently based upon the caprice and prejudice of jurors"). Such difficulties are, perhaps, to be expected from permitting lay juries free play with what is essentially civil sentencing.

In the review of punitive awards, the "shock the conscience" test has proven exceedingly difficult to apply [11] and has led to inconsistent [12] and mechanical [13] results,

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[11] *E.g., Malandris* v. *Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 703 F.2d 1152 (10th Cir. 1982) (en banc) (court divided over whether punitive award was "shocking"), *cert. denied*, 464 U.S. 824 (1983); *see generally Ace Truck & Equipment Rentals, Inc.* v. *Kahn*, No. 16350 (Nev. Nov. 30, 1987) (surveying and rejecting this and other standards; adopting "clearly disproportionate"). *See also Rowlett* v. *Anheuser-Busch, Inc.*, No. 87-1021 (1st Cir. Nov. 4, 1987). The *Rowlett* court's opinion, as originally released on September 30, 1987, included the following innovation: "[T]he court should instruct the jury as to the maximum verdict allowable . . . . the court should [also] instruct the jury that it is free to conclude against any punitive damages as well as any sum less than the maximum reasonable amount stated." On November 4, 1981, however, the panel issued an order deleting that language from the opinion.

[12] *E.g., Hatrock* v. *Jones & Co.*, 750 F.2d 767, 772-73 (9th Cir. 1984) (7:1 ratio of punitive to compensatory damages reasonable; "one-third of one percent of . . . gross revenues, and less than three percent of . . . net capital" not excessive; prior cases striking down lower ratios distinguished on ground that those cases were fact-specific).

[13] *E.g., Ogilvie* v. *Fotomat Corp.*, 641 F.2d 581, 586-87 (8th Cir. 1981) (punitive damages remitted solely because district court

perhaps because it implicitly requires reviewing judges to make not one but two determinations: (i) what an appropriate amount or range of punitive damages would be, and (ii) whether the amount actually awarded by the jury is so far from the appropriate amount or range as to be shocking. More effective control and more carefully considered, rational, and consistent results are likely to be achieved if judges are required to make only the first determination.

The district court's approach is also theoretically proper. Unlike a compensatory award, the amount of punitive damages is not inextricably tied to the issue of liability *vel non*, and thus is not a "most fundamental element" of trial by jury. *See Tull*, *supra*, 107 S. Ct. at 1840. Compensatory damages are an attempt to quantify the plaintiff's injury. Accordingly, "[c]ompensatory damages . . . are mandatory; once liability is found, the jury is required to award compensatory damages in an amount appropriate to compensate the plaintiff for his loss." *Smith* v. *Wade*, 461 U.S. 30, 52 (1983). By contrast, a "key feature" of punitive damages is that "they are never awarded as of right, no matter how egregious the defendant's conduct." *Id.* *Liability* for punishment does have a large factual component properly entrusted to the jury. Nevertheless, the appropriate *amount* of punishment turns on different factors, including punishment already imposed on the defendants in related cases and the need to deter both the defendant and others who are not before the court.

As the district court understood, those are questions more of discretion than fact—similar to questions judges resolve every day in imposing criminal fines. The amount needed to punish or deter a defendant from recidivism may be very little if he has already suffered multiple

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had remitted compensatory damages, and court of appeals wanted to restore the ratio of compensatory to punitive damages established by jury).

punitive judgments for the same act. Or, as the district court found in this case, the amount of punishment needed for deterrence may be affected by the defendant's post-trial reform. That circumstance, too, is familiar to judges from criminal sentencing. In light of the guidelines for setting fines established by the United States Sentencing Commission and now in effect, 52 Fed. Reg. 18046, 18099 (May 13, 1987), entrusting to judges the ultimate power to impose civil fines, in the same way they do criminal fines, can be expected to yield more equitable and principled results.[14] Unlike jurors, who serve in only one or a few cases, judges gain experience and sophistication by deciding how much punishment to impose in many cases.

Several commentators have suggested a variant of the district court's idea. Their proposal is that the jury determine liability for punitive damages, but that the court fix the amount without submitting that issue initially to the jury. *See e.g.*, Owen, "Problems In Assessing Punitive Damages Against Manufacturers Of Defective Products," 49 *U. Chi. L. Rev.* 1, 52 (1982); Mallor & Roberts, "Punitive Damages: Toward A Principled Ap-

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[14] Of course, if the Seventh Amendment does not require a jury to determine the amount of punitive damages, neither does Fed. R. Civ. P. 38; it only preserves "trial by jury as declared by the Seventh Amendment . . . or as given by a [federal] statute." Although there is a strong federal policy favoring trial by jury of issues of fact, *Simler* v. *Connor*, 372 U.S. 221, 222 (1963) (per cuiram), there is no such policy with respect to discretionary imposition of punitive sanctions. *Cf. Spaziano* v. *Florida*, 468 U.S. 447, 459 (1984) (no Sixth Amendment right to have jury impose sentence).

Moreover, it is settled that in a diversity case the allocation of matters between judge and jury is determined by federal, not state, law. *Simler, supra*; *Byrd* v. *Blue Ridge Cooperative*, 356 U.S. 525 (1958); *Herron* v. *Southern Pacific Co.*, 283 U.S. 91 (1951). Thus, if this Court should determine that neither the Seventh Amendment nor any federal policy requires that the amount of punitive damages be fixed by a jury, the law or practice of Kansas would not require a different result.

proach," 31 *Hastings L.J.* 639, 664-66 (1980); Owen, "Punitive Damages In Products Liability Litigation," 74 *Mich. L. Rev.* 1257, 1320-21 (1976). *See also* Sales & Cole, "Punitive Damages: A Relic That Has Outlived Its Origins," 37 *Vand. L. Rev.* 1117, 1167-68 (1984) (proposing court determination of both liability for and amount of punitive damages). Nevertheless, as described below, uncertainty about the applicability of the Seventh Amendment, along with other issues, has kept that experiment from moving forward at the federal level.[15]

The Senate has recently considered such measures in S. 100, 99th Cong., 1st Sess. § 12(c) (1985); S. 44, 98th Cong., 2d Sess. § 12(c) (1984); and S. 2631, 97th Cong., 2d Sess. § 13(c) (1982). Each bill was an effort to reform product liability law, and each contained substantially the same provision on punitive damages: "If the trier of fact determines . . . that punitive damages should be awarded to a claimant, the Court shall determine the amount of those damages." S. 100, *supra*, § 12(c); *cf.* S. 44, *supra*, § 12(c); S. 2631, *supra*, § 13(c).

S. 44 was reported out by the Senate Committee on Commerce, Science and Transportation in 1984. The bill stalled, however, partly out of concern for the constitutionality of judicial determinations of the amount of punitive damages. The committee report accompanying S. 44 specifically opined that jury determination solely of *liability* for punitive damages would satisfy the Seventh Amendment. S. Rep. No. 476, 98th Cong., 2d Sess. 59 (1984).[16] But Senator Hollings expressed the minority

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[15] At least one state already provides for judicial calculation of punitive damages. *See* Conn. Gen. Stat. Ann. § 52-240(b) (West Supp. 1986) ("If the trier of fact determines that punitive damages should be awarded, the court shall determine the amount of such damages not to exceed an amount equal to twice the damages awarded to the plaintiff").

[16] *See also* S. Rep. No. 670, 97th Cong., 2d Sess. at 55 (1982) (S.2631 provision for jury to determine liability for punitive dam-

view that that approach might infringe the Seventh Amendment. *Id.*, 101.

The applicability of the Seventh Amendment continued to be at issue in the subsequent hearings on S. 100. *See Hearings on S. 100 Before the Subcomm. on the Consumer of the Senate Comm. on Commerce, Science and Transportation*, 99th Cong., 1st Sess. 94 (1985) (Statement of David I. Greenberg, Legislative Director, Consumer Federation of America) ("Section 12 transfers the power to determine the amount of punitive damages from the jury to the judge despite the belief of many Reagan Administration officials that such a transfer is unconstitutional."); *id.*, 75 (Statement of Michael L. Williams, Counselor, Eugene OR) ("Eliminating the right to trial by jury may well be a violation of the Seventh Amendment . . . as well as bad economic and legal policy."). A similar bill currently pending in the House of Representatives, H.R. 1115, 100th Cong., 1st Sess. (1987), abandons the idea of having the court calculate punitive damages.

The construction to be placed on *Tull* is thus an important question with far-reaching consequences for the shape of the Seventh Amendment, for the ability of the federal courts to regulate juries' "wholly unpredictable" awards of punitive damages, and for the orderly progress of legislative and judicial tort reform. The present case provides the Court with an efficient vehicle for an exposition of *Tull*, and for consideration of a promising approach to effective judicial control of punitive damage awards. For these reasons, it is worthy of the Court's plenary review.[17]

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ages and for court to determine amount "preserves the claimant's constitutional right to a trial by jury").

[17] The question whether a court may consider post-trial occurrences in evaluating a punitive damage award, which so concerned the court of appeals, is almost entirely derivative of the Seventh

2. The Judgment Below—For Punitive Damages One Thousand Times Greater Than The Analogous Criminal Penalty—Violates The Excessive Fines Clause And Denies Petitioner Due Process.

The question whether the Excessive Fines Clause of the Eighth Amendment or the Due Process Clause of the Fifth Amendment generally prohibits the award of punitive damages grossly in excess of comparable criminal penalties is already before this Court in *Bankers Life & Casualty Co.* v. *Crenshaw*, No. 85-1765 (prob. juris noted, August 5, 1986). Moreover, the Court has previously stated its belief that the applicability of the Excessive Fines Clause to punitive damage awards "raise[s] important issues which, in an appropriate setting, must be resolved." *Aetna Life Insurance Co.* v. *Lavoie*, 106 S. Ct. 1580, 1589 (1986).

Petitioner argued in the court below that a $10 million punitive damage award—one thousand times the penalty prescribed by Congress under 21 U.S.C. § 333(b) for even a fraudulent mislabeiing of a product—was constitutionally excessive. See pp. 4-5, *supra*. That court summarily rejected the argument. (Pet. App. 23a).[18]

Amendment inquiry. As a matter of logic, if a court's independent review of the amount of punitive damages does not offend the Seventh Amendment, it should also not offend that Amendment—or federal policy—to have the court consider issues (properly) not before the jury. Moreover, as a matter of practice, federal courts acting on motions for remittitur already look to at least some post-trial occurrences. Thus, in *Spaeth* v. *Union Oil Co.*, 710 F.2d 1455 (10th Cir. 1983), *cert. denied*, 106 S. Ct. 1946 (1986), the court held that it was an abuse of discretion for the district court not to order a new trial on punitive damages in light of the court's post-verdict equitable relief. The court observed that "[w]hen the jury returned its verdict, it did not know that the court would later cancel [the defendant's] lease. . . . The loss of lease is a circumstance for consideration in evaluating the punitive award." 710 F.2d at 1460.

[18] Elsewhere in its opinion, the court of appeals did determine briefly, that the punitive damage award was not excessive, apparently as a matter of state law. (*See* Pet. App. 16a).

Petitioner respectfully suggests that this Court might appropriately hold this petition pending resolution of *Crenshaw*. Then, if the decision in *Crenshaw* is adverse to the claim under the Excessive Fines Clause, the Court could consider whether all or any of the issues presented in the instant case warrants plenary review, and proceed accordingly. If the Excessive Fines Clause claim is upheld in *Crenshaw*, and if the Court decides to deny *certiorari* on all questions in the instant case, the Court may wish to vacate the court of appeals' decision in this case and remand for further proceedings consistent with this Court's decision in *Crenshaw*.

3. A State-Law Tort Action, Premised Upon Inadequate Warning, Is Preempted By Federal Labeling Requirements.

In this case, the only theory of liability upheld by the jury was that Playtex's warnings were inadequate, under instructions determined by the law of Kansas. (Pet. App. 50a). The trial court specifically found, and instructed the jury (Pet. App. 48a, 53a), that the FDA had promulgated by regulation specific requirements for warnings on tampon packages, and that the Playtex warnings in issue had fully complied with those requirements. Therefore, the verdict necessarily was based on a failure of the warnings to comply with some *additional* requirements imposed by the law of Kansas.

Section 521(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a), provides (with an exception not relevant here) that

> no State . . . may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

Title 21 C.F.R. § 808.1(b) (1987)[19] (Pet. App. 68a) provides that § 360k applies to state requirements "(whether established by statute, ordinance, regulation, or court decision)." Tampons such as those at issue here are "devices" within the meaning of § 360k. The requirements of 21 C.F.R. § 801.430 (1987)[20] (Pet App. 66a-67a) with respect to tampon warnings are "requirement[s] applicable under [the] Act." Thus, the question is squarely presented whether additional requirements imposed under state law and made applicable through a tort action are expressly preempted by § 360k.

This issue is of great practical importance for products liability actions involving medical devices regulated by FDA. For example, as of November 30, 1987, there were 168 such actions and claims currently pending against Playtex alone. An analogous question has arisen under the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331, *et seq.* (Supp. III 1985).[21]

In view of the unchallenged finding by the trial judge that the warnings in issue complied with the specific FDA regulations applicable to tampon warnings, the question of the consistency of the verdict with § 360k is purely one of law. As a matter of law, the verdict, premised on additional requirements imposed under Kansas law, is plainly contrary to and preempted by

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[19] Section 808.1(b) has been unchanged since 1980 and was in effect at all relevant times.

[20] Section 801.430 has been unchanged since 1982 and was in effect at all relevant times.

[21] *See Palmer* v. *Liggett Group, Inc.*, 825 F.2d 620 (1st Cir. 1987); *Stephen* v. *American Brands, Inc.*, 825 F.2d 312 (11th Cir. 1987); *Cipollone* v. *Liggett Group, Inc.*, 789 F.2d 181 (3rd Cir. 1986), *cert. denied*, 107 S. Ct. 907 (1987).

§ 360k.[22] Thus, although the issue was not formally raised below, there is no practical impediment to its determination by this Court.[23]

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[22] To date, at least six district courts have considered this question. Five have held state-law actions preempted: *Perotta* v. *International Playtex, Inc.*, No. 86-8099-CIV-KEHOE (S.D. Fla. Nov. 9, 1987); *Stewart* v. *International Playtex, Inc.*, No. C/A 9:86-2817 (D.S.C. Oct. 8, 1987); *Kelchner* v. *International Playtex, Inc.*, No. 84-1426 (M.D. Pa. Sept. 1, 1987); *Ignace* v. *Playtex Family Products, Inc.* No. 86-C-480-C (W.D. Wis. Aug. 19, 1987); *Edmondson* v. *International Playtex, Inc.* No. C85-306R (N.D. Ga. June 16, 1987). One has held state-law actions not preempted. *Muzatko* v. *International Playtex, Inc.* No. 85-C-1540 (E.D. Wis. May 14, 1987).

[23] Petitioner did argue, in its motion for judgment notwithstanding the verdict or new trial, that the court's instructions on punitive damages "violate[d] the Supremacy Clause" because they frustrated "the federal government's role" in the regulation of tampons. Petitioner also argued in the court of appeals that its compliance with the FDA requirements rendered it immune from punitive damages "as a matter of law," although the main thrust of that argument invoked state law. And during the pendency of its petition for rehearing, petitioner called the cited provisions to the attention of the court of appeals in a supplementary letter, pursuant to Fed. R. App. P. 28(j). In that letter, petitioner urged that court to take judicial notice of § 360k and its effect. It is, of course, settled that the failure of a party adequately to raise an issue in a lower federal court does not deprive this Court of jurisdiction to decide it. *Carlson* v. *Green*, 446 U.S. 14, 17 n.2 (1980). Where, as here, the question is a purely legal one, it may be especially appropriate for this Court's review. *Cf. Mitchell* v. *Forsyth*, 472 U.S. 511, 530 (1985); *Nixon* v. *Fitzgerald*, 457 U.S. 731, 743 n.23 (1982). Indeed, "the Court may consider a plain error" not raised even in the petition. Sup. Ct. R. 34.1(a); *Washington* v. *Davis*, 426 U.S. 229, 238 & n.9 (1976).

CONCLUSION

For the foregoing reasons, the writ should be granted.

Respectfully submitted,

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DATED: December 21, 1987.

APPENDICES

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APPENDIX A

UNITED STATES COURT OF APPEALS
TENTH CIRCUIT

Nos. 85-1861, 85-1887

KELLY M. O'GILVIE, individually, and as ADMINISTRATOR OF THE ESTATE OF BETTY L. O'GILVIE, deceased; and STEPHANIE L. O'GILVIE, a minor, and KEVIN M. O'GILVIE, a minor, BY AND THROUGH KELLY M. O'GILVIE, their father and natural guardian,

Plaintiffs-Appellants,
Cross-Appellees,

v.

INTERNATIONAL PLAYTEX, INC.,

Defendant-Appellee,
Cross-Appellant,

MOTOR VEHICLE MANUFACTURERS ASSOCIATION, INC., PRODUCT LIABILITY ADVISORY COUNCIL, INC., and GULF & GREAT PLAINS LEGAL FOUNDATION,

Amici Curiae.

June 18, 1987

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and Grace M. Healy of Olwine, Connelly, Chase, O'Donnell & Weyher, New York City, and Larry W. Wall of Stratton, Russell, Toomey & Wall, Wichita, Kan., of counsel), for defendant-appellee, cross-appellant.

Aaron D. Twerski, Professor of Law, Hofstra University School of Law, Hempstead, N.Y., Marc R. Brosseau of Weller, Friedrich, Hickisch, Hazlitt & Ward, Denver, Colo. (William H. Crabtree and Edward P. Good, Motor Vehicle Manufacturers Ass'n of the United States, Detroit, Mich., of counsel), filed a brief on behalf of amici curiae Motor Vehicle Manufacturers Ass'n, Inc. and Product Liability Advisory Council, Inc.

Jerald L. Hill and Mark J. Bredemeier of Gulf & Great Plains Legal Foundation, Kansas City, Missouri, filed a brief on behalf of amicus curiae Gulf & Great Plains Legal Foundation.

Before McKAY, SETH, and SEYMOUR, Circuit Judges.

SEYMOUR, Circuit Judge.

Kelly O'Gilvie brought this diversity action, individually and on behalf of the estate of his deceased wife Betty, against International Playtex, Inc. O'Gilvie alleged that Betty's use of Playtex super-absorbent tampons caused her death from toxic shock syndrome, and he sought damages from Playtex under the Kansas law of strict liability in tort. In answers to special interrogatories, the jury found that Playtex tampons had caused Mrs. O'Gilvie to develop toxic shock syndrome, and that Playtex had failed to adequately warn of the fatal risk of toxic shock from the use of its product. The jury awarded actual damages of $1,525,000,[1] and punitive damages of $10,000,000. After the entry of judgment and

[1] The jury attributed 80% of the total fault to Playtex and 20% to Dr. Hays, Betty's physician, who was not a party to the lawsuit. Accordingly, the court entered judgment against Playtex for 80% of the total amount of actual damages.

apparently in response to the trial court's suggestion, Playtex represented that it was discontinuing the sale of some of its products, instituting a program of alerting the public to the dangers of toxic shock syndrome, and modifying its product warning. The court thereupon ordered the punitive damage award reduced to $1,350,000.

Both parties have appealed. O'Gilvie contends that the court abused its discretion by reducing the amount of the punitive damages award. Playtex asserts: 1) it was entitled to a directed verdict because there was no evidence that the warning was inadequate or that it caused the injury; 2) the court erred in refusing to allow the jury to consider the fault of Betty O'Gilvie or the fault of other tampon manufacturers; and 3) the court erred in submitting the issue of punitive damages to the jury. We find no ground for disturbing the liability verdict against Playtex. We conclude, however, that the court's order reducing the punitive damage award must be reversed.

I.

A review of the record reveals the following sequence of events. On Tuesday, March 29, 1983, Betty O'Gilvie attended hairdressing school all day. While there, she told a friend that she had a sore throat and a vaginal yeast infection all weekend, and that she was going to call her doctor. Mrs. O'Gilvie's husband testified that he first became aware she was not feeling well on Wednesday morning, March 30. She told him she thought she had a cold or the flu. Mrs. O'Gilvie's sister, Cheryl Ballway, took Mrs. O'Gilvie to the office of her physician, Dr. Hays, the morning of March 30 for a 9:30 a.m. appointment. Although Ms. Ballway testified that Mrs. O'Gilvie said she was suffering from vomiting and diarrhea, the doctor testified that Mrs. O'Gilvie did not mention these symptoms to him. Mr. O'Gilvie testified that his wife did not have these symptoms at any time before she went to Dr. Hays.

When Mrs. O'Gilvie asked Dr. Hays about toxic shock syndrome, he assured her that she did not have it and diagnosed scarlet fever. Mrs. O'Gilvie's temperature rose to 105° by Wednesday evening, and Mr. O'Gilvie testified that she had more or less lost consciousness. He called Dr. Hays at about 10 p.m., and Dr. Hays reassured him that the scarlet fever was running its course. The doctor instructed him to continue giving Mrs. O'Gilvie aspirin, fluids, and the prescribed medication. Mrs. O'Gilvie's mother-in-law, who was caring for her, called Dr. Hays' office at about 9 a.m. Thursday, March 31. She did not speak with Dr. Hays and was told by office personnel to continue the treatment. Mrs. O'Gilvie's condition steadily deteriorated Thursday morning, and her mother-in-law called the office at 1:30 p.m. to report that Mrs. O'Gilvie's fingers were turning blue. Shortly thereafter Mrs. O'Gilvie was brought to the office, emergency measures were begun, and she was rushed to the hospital. She died Saturday, April 2, of toxic shock syndrome.

II.

Playtex contends that it was entitled to a directed verdict because O'Gilvie presented no evidence that the warning accompanying its super-absorbent tampons was inadequate or that the warning was the cause of Mrs. O'Gilvie's injury. We disagree. A directed verdict is not proper if the record, viewed most favorably to the party opposing the motion, contains evidence upon which a reasonable jury could return a verdict for the nonmoving party. *See Cockrell v. Boise Cascade Corp.*, 781 F.2d 173, 177 (10th Cir.1986); *Mackey v. Burke*, 751 F.2d 322, 325 (10th Cir.1984).

O'Gilvie argued at trial that the warning was inadequate because it did not properly apprise users of the causal connection between toxic shock and the use of tampons, or of the increased risk from the use of super-

absorbent tampons.[2] The record contains substantial expert testimony that a causal link exists between toxic

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[2] The warning on the outside of the Playtex package stated:

"Attention: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information."

Brief of Defendant-Appellee, Cross-Appellant at 7. The package insert stated:

"*WARNING SIGNS*

WARNING SIGNS OF TSS FOR EXAMPLE ARE: SUDDEN FEVER (USUALLY 102° OR MORE) AND VOMITING, DIARRHEA, FAINTING OR NEAR FAINTING WHEN STANDING UP, DIZZINESS, OR A RASH THAT LOOKS LIKE A SUNBURN.

"IF THESE OR OTHER SIGNS OF TSS APPEAR, YOU SHOULD REMOVE THE TAMPON AT ONCE, DISCONTINUE USE, AND SEE YOUR DOCTOR IMMEDIATELY.

"There is a risk of TSS to all women using tampons during their menstrual period. TSS is a rare but serious disease that may cause death. The reported risks are higher to women under 30 years of age and teenage girls. The incidence of TSS is estimated to be between 6 and 17 cases of TSS per 100,000 menstruating women and girls per year.

"You can avoid any possible risk of getting tampon-associated TSS by not using tampons. You can possibly reduce the risk of getting TSS during your menstrual period by alternating tampon use with sanitary napkin use and by using tampons with the minimum absorbency. Playtex makes Regular absorbency tampons for lighter flows and Super and Super Plus absorbencies for heavier flows.

"If you have had warning signs of TSS in the past, you should check with your doctor before using tampons again.

"Information about TSS on the package and in this insert are provided by Playtex in the public interest and in accordance with the Food and Drug Administration (FDA) tampon labeling requirements. TSS is believed to be a recently identified condition caused by a bacteria called staphylococcus aureus. The FDA does not maintain that tampons are the cause of TSS. The FDA recognizes that TSS also occurs among nonusers of tampons.

"If you have any questions about TSS or tampon use, you should check with your doctor."

Id. at Addendum A.

shock and the use of super-absorbent tampons such as the Playtex product at issue here. Experts also testified that the warning did not alert buyers to the increased risk from use of high-absorbency tampons, and that simply mentioning an association between toxic shock and tampon use did not adequately alert users to the cause and effect relationship. Indeed, Playtex' own expert, Dr. David Hall, testified that *if* Playtex tampons *cause* toxic shock, the Playtex package warning was inadequate. *See* rec., vol. 25, at 2690, 2721, 2723.

Playtex' argument that there is no evidence of a causal connection between the inadequacy of the warning and the injury is also without merit. Under Kansas law, an inadequate warning creates a presumption of causation. *See Wooderson v. Ortho Pharmaceutical Corp.*, 235 Kan. 387, 681 P.2d 1038, 1057 (1984). This presumption, considered together with Kelly O'Gilvie's testimony on the consideration his wife would have given an adequate warning, was sufficient to send the causation issue to the jury.

Playtex also argues that its warning was adequate as a matter of law because it complied with Food and Drug Administration (FDA) regulations. In the alternative Playtex contends that the court's instruction on the effect of compliance with FDA requirements was erroneous. We are not persuaded by these arguments.

The district court instructed the jury as a matter of law that the Playtex package warning was in conformity with FDA regulations, and further instructed:

> "If the warning on the product was, at the time of manufacture, in compliance with administrative regulatory safety standards relating to warnings or instructions, then such warning is evidence of due care, and the product shall be deemed not defective by reason of the warning or instructions, unless the plaintiff proves that a reasonably prudent manufac-

turer could and would have taken additional precautions.

"In other words, you are instructed that even if you find that defendant International Playtex met all government regulations and requirements, which are minimum standards, such compliance is not a defense if a reasonable and prudent manufacturer would have taken added precautions."

Rec., vol. 1, at 129.

On appeal, Playtex contends that the court erred in this instruction by characterizing the FDA requirements as minimum standards. This argument fails on two grounds. Although the record bristles with objections by everyone to virtually everything on every conceivable ground, Playtex did *not* object to this instruction on that ground. *See*, rec., vol. 29, at 3364-65. Moreover, the instruction is an accurate reflection of the law of Kansas. *See* Kan. Stat.Ann. § 60-3304 (1983); *Jones v. Hittle Serv., Inc.*, 219 Kan. 627, 549 P.2d 1383 (1976).

We also reject Playtex' argument that its compliance with FDA standards entitled it to judgment as a matter of law. Compliance is not dispositive under Kansas law if the plaintiff shows that a reasonable manufacturer would have done more. O'Gilvie presented ample evidence that mere compliance with the FDA standards was not adequate under the circumstances. The court therefore properly sent the issue to the jury.[3]

III.

Playtex contends that it is entitled to a new trial because the district court refused to allow the jury to

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[3] Playtex also complains on appeal that the trial judge improperly remarked to the jurors that after hearing the evidence in this case, they knew more about toxic shock syndrome than the FDA. Playtex did not assert this as error below, and we will therefore not consider it here.

consider the issue of the comparative fault of Betty O'Gilvie or of other tampon manufacturers.

A.

Playtex correctly points out that, under Kansas law, "all types of fault, regardless of degree, are to be compared with that of defendant whether the fault is characterized as contributory negligence, assumption of risk, product misuse, or unreasonable use. All of these defenses depend on the reasonableness of plaintiff's conduct, a negligence concept." *Prince v. Leesona Corp.*, 720 F.2d 1166, 1171 (10th Cir. 1983) (citing *Kennedy v. City of Sawyer*, 228 Kan. 439, 618 P.2d 788, 796-97 (1980)). Playtex argues that Mrs. O'Gilvie's fault should have been submitted to the jury because

> "(1) She read and understood the warnings accompanying the Playtex tampons (Tr. 2511); (2) knowing this risk she chose to use tampons; (3) despite skepticism about Dr. Hays's diagnosis (Tr. 2513), she did not seek a second medical opinion; (4) after developing the symptoms associated with TSS she continued to use tampons (Tr. 2513); and, (5) she did not return to her doctor or see another doctor although the symptoms persisted and worsened."

Brief of Defendant-Appellee, Cross-Appellant at 22-23.

A plaintiff is contributorily negligent when his conduct is a contributing cause of the harm and falls short of that which a reasonable person would undertake for his own protection. *See Allman v. Holleman*, 233 Kan. 781, 667 P.2d 296, 300 (1983). The doctrine of assumption of the risk requires the defendant to "prove that the injured plaintiff (1) discovered the defect; (2) was aware of the danger; and (3) unreasonably continued to use the product." *Prince*, 720 F.2d at 1169. "Both doctrines require some knowledge of the danger or risk." *Guerra v. Jaeger*, 204 Kan. 309, 461 P.2d 737, 741

(1969). A defendant who seeks to reduce his percentage of fault by comparing it to the fault of another party has the burden of proving by a preponderance of the evidence that the party was at fault and that the fault caused or contributed to the injury. *See Wooderson*, 681 P.2d at 1058.

For purposes of assessing the evidence regarding Mrs. O'Gilvie's comparative fault, we must look separately at her conduct before her first visit to Dr. Hays, and her conduct after that time. Mrs. O'Gilvie's conduct *after* her initial visit to Dr. Hays could not give rise to a jury issue on her comparative fault because her continued use of tampons after the visit was not negligent as a matter of Kansas law. In *Allman*, the defendant claimed that the decedent had been contributorily negligent in taking birth control pills. The Kansas Supreme Court disagreed, pointing out that the decedent had taken the pills pursuant to a doctor's prescription.

> "This fact, along with the widespread disregard of warning labels on packages, prohibits a finding of fault on the part of Ms. Allman. Even though there is a recognizable risk, conduct, to be negligent, must be unreasonable. Prosser, Law of Torts § 31 (4th ed. 1971). As we are becoming constantly more aware, nearly all human acts carry with them some degree of risk. When that risk is slight enough that it is commonly disregarded, however, the standard of ordinary care is not violated. Such is the case here with the taking of birth control pills."

667 P.2d at 300. Similarly, Mrs. O'Gilvie continued her use of tampons after being reassured by her doctor that she did not have toxic shock. The rationale of *Allman* clearly precludes a finding that Mrs. O'Gilvie's disregard of the package warning under these circumstances was unreasonable.

Even Playtex does not argue that Mrs. O'Gilvie was at fault merely in using tampons. Rather, Playtex contends that her conduct was unreasonable because she failed to discontinue their use after she developed the symptoms of toxic shock syndrome, which she recognized, and because she did not seek a second medical opinion despite skepticism about Dr. Hays' diagnosis. This is so, it says, because its warning told her to discontinue use and see a doctor if she got the described symptoms.

Mrs. O'Gilvie's conduct in continuing to use tampons could be unreasonable only if the Playtex warning adequately advised her of the danger. *See, e.g., Billiar v. Minnesota Mining & Mfg. Co.*, 623 F.2d 240, 245 (2d Cir.1980). Indeed, in its proposed jury instruction on Mrs. O'Gilvie's comparative fault, Playtex stated:

> "In regard to Betty O'Gilvie's negligence, the defendants allege that if Betty O'Gilvie had toxic shock syndrome, she had knowledge of the risk of TSS with tampon use and chose to accept that risk, *and* that she *continued to use tampons with knowledge of the warning contained in the package, and* that *such conduct contributed to cause* any injury or damage she may have suffered. If you find that Mrs. O'Gilvie acted in such manner, you must find that she was negligent and at fault."

Rec., vol. 1, at 52 (emphasis added). A defendant may not limit its liability by relying on a plaintiff's failure to heed an *insufficient* warning. *See, e.g., Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1538-39 (D.C.Cir.), *cert. denied*, 469 U.S. 1062, 105 S.Ct. 545, 83 L.Ed.2d 432 (1984); *Billiar*, 623 F.2d at 245. In essence, the issue of the adequacy of the warning, which went to the jury, resolves any issue of Mrs. O'Gilvie's fault as well. *See Billiar*, 623 F.2d at 245-46. If the jury had decided that the warning was adequate, Playtex would not have been

liable and Mrs. O'Gilvie's fault in not following the warning would have been irrelevant. Instead, the jury decided the warning was inadequate, and this finding is dispositive of the comparative fault issue because failure to heed an inadequate warning is not unreasonable. Playtex' argument on appeal that Mrs. O'Gilvie was at fault in disregarding a warning that did not properly apprise her of the very hazard to which she fell victim is simply without legal or logical support. *See Ferebee*, 736 F.2d at 1538-39; *Billiar*, 623 F.2d at 245; *see generally* 4 F. Harper, F. James, Jr. & O. Gray, The Law of Torts § 20.5, at 147-61, § 22.15, at 393-94 (1986).

B.

Nor do we agree with Playtex' assertion that the trial court erred in failing to allow the jury to assess the comparative fault of the manufacturers of Kotex and Tampax products. Comparison of the fault of these other manufacturers is precluded because it was not timely raised by Playtex as required by *Hardin v. Manitowoc-Forsythe Corp.*, 691 F.2d 449 (10th Cir.1982).[4] In *Hardin*, as here, we were concerned with the propriety of allowing the jury to assess comparative fault when the issue had not been properly raised in the pleadings or the pretrial order. We pointed out that "[this] circuit permits a post-judgment amendment of a pretrial order to conform to the evidence if an issue has been tried with the express or implied consent of the parties and not over objection." *Id.* at 456. "Implied consent is found where the parties recognized that the issue entered the case at trial and acquiesced in the introduction of evidence on that issue without objection." *Id.* at 457. The defense that a phan-

[4] Moreover, the evidence discloses that the only time Mrs. O'Gilvie used a Tampax product was at 11 a.m. on Thursday, March 31, when one was inserted by her mother-in-law. The evidence is undisputed that by that time Mrs. O'Gilvie was already so ill that she had virtually no chance of survival.

tom party contributed to a plaintiff's injury is in the nature of an avoidance, and normally would be required under Fed.R.Civ.P. 8(c) to be pleaded affirmatively in the answer. *Id.* at 458. "[B]ecause the major purpose of Rule 8(c) is to provide particularized notice of certain matters, courts must be particularly careful to scrutinize the record to ensure that plaintiff had adequate notice and opportunity to rebut the tardily-raised Rule 8(c) defense before finding that it was tried by consent." *Id.*

Scrutiny of the record in this case reveals circumstances far more egregious than those the court held in *Hardin* to have denied the plaintiff a fair opportunity to respond. *See id.* at 459. Playtex did not raise this comparative fault issue in its pleadings, the pretrial order, or the pretrial hearing. Playtex filed its first set of requested jury instructions on January 18, 1985, four days before the trial started. These instructions contained references to the comparative fault of Mrs. O'Gilvie and Dr. Hays, but did not mention the fault of other manufacturers. On February 4, 1985, over a week into the trial, Playtex filed a supplement to its requested instructions that likewise did not propose an instruction on other manufacturers' fault. On February 14, after plaintiff had rested, Playtex presented as its first witness Mrs. O'Gilvie's sister, Cheryl Ballway, whom it had not specifically listed as a witness. Ms. Ballway testified that she had purchased all of Mrs. O'Gilvie's sanitary products and that she always purchased Kotex tampons for Mrs. O'Gilvie. She also testified that she gave her sister a Kotex tampon on the way home from the doctor's office.[5]

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[5] We note that Ms. Ballway's testimony was substantially impeached by rebuttal evidence that, the day after Mrs. O'Gilvie died, a Playtex tampon was found in the purse she had taken to Dr. Hays' office and a box of Playtex tampons was found in her bathroom. There was also rebuttal evidence that Ms. Ballway blamed her sister's husband and his mother for the death. Finally, the record discloses that Ms. Ballway was the one who originally con-

As the judge recognized, this evidence caught plaintiff and the court by surprise. *See*, rec., vol. 25, at 2590-92.

Also on February 14, Playtex filed a motion for reconsideration of the denial of its request for a directed verdict. In this motion, Playtex argued that the sister's testimony barred plaintiff's claim because this evidence established that Mrs. O'Gilvie had not used Playtex tampons at all, and that they were therefore *not* the cause in fact of her death. Rec., vol. 1, at 58-59. This argument, which framed the use question as an either/or issue, is logically at odds with the concept of comparative negligence. It therefore could not provide notice that Playtex was asserting this defense. The court denied the motion, ruling that Mrs. O'Gilvie's use of Playtex tampons was a fact issue for the jury to resolve. The jury returned a special verdict finding that Mrs. O'Gilvie had used the Playtex product.

Not until February 22, the day the case was sent to the jury, did Playtex raise the issue of other manufacturers' comparative fault by filing a proposed jury instruction and a verdict form that would have allowed the jury to assess the fault of other manufacturers. Thus, Playtex did not inject this issue into the case even indirectly until *after all the evidence had been presented* and the parties had rested. It would be a miscarriage of justice to require a new trial on an issue that Playtex did not raise until it was too late for plaintiff to rebut. Such a result would be directly contrary to our holding in *Hardin*.

IV.

We turn to the issues involving the punitive damages awarded in this case. Playtex contends that the district court erred in submitting the issue of punitive damages

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tacted plaintiff's lawyer and gave him the name of Playtex to sue, and that she believed she should have been able to bring the action rather than Mr. O'Gilvie.

to the jury, and that the size of the award is excessive. O'Gilvie argues that the court erred in reducing the amount assessed by the jury solely as a result of events occurring after the verdict had been returned.

A.

Punitive damages are imposed under Kansas law for "a willful and wanton invasion of the injured party's rights, the purpose being to restrain and deter others from the commission of like wrongs." *Wooderson*, 681 P.2d at 1061 (quoting *Cantrell v. Amarillo Hardware Co.*, 226 Kan. 681, 686, 602 P.2d 1326, 1331 (1979)).

> "In assessing punitive damages the nature, extent, and enormity of the wrong, the intent of the party committing it, and all circumstances attending the transaction involved should be considered. Any mitigating circumstances which may bear upon any of the above factors may be considered to reduce such damages."

Id. (quoting *Henderson v. Hassur*, 225 Kan. 678, 594 P.2d 650, 663 (1979)).

Our review of the record reveals abundant evidence that Playtex deliberately disregarded studies and medical reports linking high-absorbency tampon fibers with increased risk of toxic shock at a time when other tampon manufacturers were responding to this information by modifying or withdrawing their high-absorbency products. Moreover, there is evidence that Playtex deliberately sought to profit from this situation by advertising the effectiveness of its high-absorbency tampons when it knew other manufacturers were reducing the absorbency of their products due to the evidence of a causal connection between high absorbency and toxic shock. This occurred in the face of Playtex' awareness that its product was far more absorbent than necessary for its intended effective-

ness.[6] In our view, this evidence is sufficient to create a jury issue on whether Playtex was "grossly negligent or recklessly indifferent to the rights of others." *Wooderson*, 681 P.2d at 1062.

Playtex argues that the presence of a warning that complied with FDA requirements precludes, as a matter of law, any finding that Playtex exhibited the reckless indifference necessary to support an award of punitive damages. We disagree. As we noted above, compliance with FDA standards is not dispositive under Kansas law if a reasonable manufacturer would have done more. Under these circumstances, compliance with the FDA regulations does not preclude punitive damages when there is evidence sufficient to support a finding of reckless indifference to consumer safety.

Playtex also asserts that the punitive damages awarded in this case are excessive. The trial court disagreed. *See infra* at 1448. In *Binyon v. Nesseth*, 231 Kan. 381, 646 P.2d 1043 (1982), the Kansas Supreme Court set out the following factors relevant to an award of such damages:

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[6] Plaintiff's exhibit 6 is an internal Playtex memorandum establishing the belief by certain Playtex employees that the Playtex super deodorant tampon was exceptionally over-absorbent. After comparing the tampon's absorbency with the average menstrual flow, the writer stated, "[c]onsidering the foregoing, our tampons are similar to automobiles which can achieve a speed of 300 miles an hour, but with which 90% of the drivers will never exceed 55 miles per hour and the remainder will *occasionally* drive at speeds up to 90 miles per hour." Rec., vol. 2, at 257 (emphasis in original). After noting that leakage was the original reason for increasing tampon absorbency, the writer stated:

> "In being obsessed with 'absorbency' we lost sight of the fact that 'leakage' complaints did not decrease as the tampon absorbency potentials were increased. Like the definition of a fanatic 'one who redoubles his efforts because he has lost sight of his goals', we then converted our heavier weight tampons to PA fiber, providing even more 'absorbency' and in fact threw in a 3.8 g PA 'Super Plus' for good measure."

Id.

> "The law establishes no fixed ratio between actual and exemplary damages by which to determine excessiveness. In assessing punitive damages the nature, extent, and enormity of the wrong, the intent of the party committing it, and all circumstances attending the transaction involved should be considered. Any mitigating circumstances which may bear upon any of the above factors may be considered to reduce such damages. *Will v. Hughes*, 172 Kan. 45, 55, 238 P.2d 478 (1951). In fixing an award of punitive damages a jury may consider the amount of actual damages recovered, defendant's financial condition and the probable litigation expenses."

Id., 646 P.2d at 1047 (quoting *Henderson*, 225 Kan. at 694, 594 P.2d at 663 (1979)). "Any jury award of punitive damages involves a 'discretionary moral judgment.'" *Silkwood v. Kerr-McGee Corp.*, 769 F.2d 1451, 1461 (10th Cir.1985) (quoting *Smith v. Wade*, 461 U.S. 30, 52, 103 S.Ct. 1625, 1638, 75 L.Ed.2d 632 (1983)), *cert. denied*, —— U.S. ——, 106 S.Ct. 1497, 90 L.Ed.2d 356 (1986). We have reviewed the record in light of these factors. Given the fnancial worth of Playtex and the number of consumers whose safety was potentially impacted by Playtex' conduct with respect to this product, we agree with the trial court that the amount of punitive damages is not excessive.

B.

Finally, we reach O'Gilvie's argument that the trial court exceeded its authority when it reduced the amount of the punitive damage award. As an initial matter, we address Playtex' contention that we are without jurisdiction to reach this issue.

Playtex argues that O'Gilvie accepted the remittitur, and therefore waived the right to appeal. "[A] plaintiff in federal court, whether prosecuting a state or federal cause of action, may not appeal from a remittitur order

he has accepted." *Donovan v. Penn Shipping Co.*, 429 U.S. 648, 650, 97 S.Ct. 835, 837, 51 L.Ed.2d 112 (1977) (per curiam).

We have reviewed the record on this matter, and find no evidence that O'Gilvie consented to the remittitur or was given an opportunity to do so. On March 21, 1985, the trial court held a hearing on Playtex' post-trial motions, including a motion to remit both the compensatory and punitive damages. After hearing arguments on the issue, the court stated, "this jury's verdict as to punitive damages will presently stand." Rec., vol. 30, at 3525. The court then stated that it wanted to extend another option to Playtex and suggested that it would reconsider remittitur if Playtex would agree to take its high-absorbency product off the market. Although the court stated its *belief* that plaintiff's counsel would accept such a trade-off, there is no such statement on the record by plaintiff's counsel. The court ordered a hearing on Playtex' response to his suggestion eventually set for May 24. The record does not contain a transcript of such a hearing, and the docket sheet does not indicate that a hearing was held on that date. Instead, on May 24, the district court filed a document styled Remittitur of Punitive Damages, ordering the reduction. The order does not offer O'Gilvie the option of accepting the remittitur in lieu of a new trial, and the record contains no indication that O'Gilvie was ever given any choice in the matter. Under these circumstances, we hold that O'Gilvie is not precluded from challenging the propriety of the remittitur on appeal.[7]

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[7] Plaintiff did not argue below, as he does here, that the trial court was without authority to reduce the punitive damages because of the post-trial conduct of Playtex. Given the unusual sequence of events as described above, and the public importance of this issue, we elect to address the remittitur question in the interest of justice. *See Hansen v. Heckler*, 783 F.2d 170, 174 n.4 (10th Cir. 1986).

Alternatively, Playtex argues that a remittitur is an interlocutory order because the plaintiff must be given the option of accepting a new trial as an alternative to accepting the remittitur, and the grant of a new trial is not appealable until after the second trial has been held.

Playtex is correct that in an ordinary remittitur case, the plaintiff must be offered a choice between a new trial and accepting a remittitur to avoid a serious problem under the Seventh Amendment, which reserves to the jury the determination of damages. *See Kennon v. Gilmer*, 131 U.S. 22, 28-30, 9 S.Ct. 696, 698-99, 33 L.Ed. 110 (1889); *McKinnon v. City of Berwyn*, 750 F.2d 1383 (7th Cir.1984); *see also* 11 C. Wright & A. Miller, Federal Practice and Procedure § 2815, at 99 (1973); Note, *Civil Procedure—Remittitur of Punitive Damages in Exchange for Product Recall—O'Gilvie v. International Playtex*, 34 Kan.L.Rev. 823, 833-34 (1986). In the usual remittitur situation, a trial judge reviews the jury's verdict in order to determine if substantial evidence at trial supported the amount awarded. If the court finds that insufficient evidence exists, or finds the amount of the verdict a product of jury passion or prejudice, the court then may determine a reasonable amount as plaintiff's damages and allow plaintiff to remit the excess over such amount. *See Malandris v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 703 F.2d 1152, 1168 (10th Cir.1981) (en banc) (plurality opinion), *cert. denied*, 464 U.S. 824, 104 S.Ct. 92, 78 L.Ed.2d 99 (1983); *J.T. Majors & Son, Inc. v. Lippert Bros., Inc.*, 263 F.2d 650, 655-56 (10th Cir. 1958). In the event plaintiff refuses to remit the excess, the court must then order a new trial on the damages issue. Playtex is also correct that ordinarily a plaintiff cannot immediately appeal the grant of a new trial when he has rejected the remittitur. *See Kanatser v. Chrysler Corp.*, 195 F.2d 104, 105 (10th Cir.1952); *see also Higgins v. Smith Int'l, Inc.*, 716 F.2d 278, 281 (5th Cir. 1983); *Eaton v. Nat'l Steel Prods. Co.*, 624 F.2d 863, 864

(9th Cir.1980); *Evans v. Calmar S.S. Co.*, 534 F.2d 519, 522 (2d Cir.1976). Given our conclusion below that this is not an ordinary remittitur case because the trial court lacked the power to order a remittitur based on post-trial occurrences, we hold that the cited cases are not applicable and that we have jurisdiction over the appeal.

Under both federal and Kansas law, remittitur is not proper unless the amount of damages awarded is so excessive that it shocks the judicial conscience. *See, e.g., Malandris*, 703 F.2d at 1168; *Henderson v. Hassur*, 225 Kan. 678, 594 P.2d 650, 665 (1979). To the extent this determination involves procedural issues or requires an examination of the sufficiency of the evidence to support the verdict, the inquiry is governed by federal law. *See Donovan*, 429 U.S. at 649-50, 97 S.Ct. at 836-37; *K-B Trucking Co. v. Riss Int'l Corp.*, 763 F.2d 1148, 1162 (10th Cir.1985); 19 C. Wright, A. Miller & E. Cooper, Federal Practice and Procedure § 4511, at 179 (1982). However, the circumstances under which punitive damages are available in a diversity case are governed by state law, *see Spaeth v. Union Oil Co.*, 710 F.2d 1455, 1459-60 (10th Cir.1983); *Saval v. BL Ltd.*, 710 F.2d 1027, 1033 (4th Cir.1983), as are the substantive elements upon which an award of punitive damages may be based, *see Spaeth*, 710 F.2d at 1460; *Malandris*, 703 F.2d at 1177. Thus, an assessment of the propriety of awarding punitive damages and the sufficiency of the evidence to support the award must necessarily be made by reference to the factors that the state has deemed relevant in determining whether punitive damages are appropriate.

In this case, the judge reviewed his notes on the evidence supporting the award of punitive damages at the post-trial hearing and stated that he was "satisfied there was sufficient evidence there" and "that the jury's answers were intelligently drawn, they were not drawn out of passion or prejudice, they understood this evidence." Rec., vol. 30, at 3517. The judge also stated that "the

amount of the verdict does not bother me, nor shock my conscience, and in light of the findings the jury made I'm not surprised with it." *Id.* at 3524. He then declared that had O'Gilvie been allowed to seek punitive damages of $20,000,000, an award for that amount would not have been a surprise to him and would not have been remitted.

Notwithstanding the court's ruling that the punitive damages verdict was supported by the evidence, was not excessive, and did not shock its conscience, it assured counsel for Playtex that substantial modification or complete remittitur would be forthcoming if Playtex should decide to remove its super-absorbent tampons from the market. In so doing, the court stated its view that this verdict was only the beginning, and that other cases would follow.

We find no authority in either the relevant federal or state law that would permit a trial court to remit a punitive damage award under the circumstances of this case. This court has said that, as a matter of federal law,

> "*absent an award so excessive as to shock the judicial conscience and to raise an irresistible inference that* passion, prejudice, corruption or other *improper cause invaded the trial*, the jury's determination of the damages is considered inviolate."

Malandris, 703 F.2d at 1168 (emphasis added). The trial court's action here violated this standard both because it expressly found that the award did *not* shock its judicial conscience and because it based its decision to remit on events occurring after trial.[8]

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[8] Playtex relies on *Spaeth v. Union Oil Co.*, 710 F.2d 1455 (10th Cir. 1983), as support under federal law for the court's remittitur here. That case is distinguishable on the very grounds set forth above. In *Spaeth*, a remittitur was ordered after this court had considered the events occurring prior to trial and at trial, and based on those events had concluded that the punitive damage award was

Nor do we find any support for the court's action in the substantive law of Kansas. The Kansas Supreme Court has clearly ruled that the only factors relevant to a punitive damage award are those involving "the quality of the character of the tortious act itself." *Ettus v. Orkin Exterminating Co.*, 233 Kan. 555, 665 P.2d 730, 741 (1983). In *Ettus*, the defendant Orkin contended that the trial court erred in refusing to admit evidence of Orkin's attempts to settle the claim at issue. Orkin sought to present this evidence to show mitigating circumstances in defense of the plaintiff's claim for punitive damages. *Id.*, 665 P.2d at 739-40. In upholding the trial court, the supreme court pointed out:

> "Many elements enter into settlement negotiations and offers which have no bearing whatsoever on the culpability of the defendant for the alleged wrongful conduct. Availability of witnesses or other critical evidence, the financial condition of the parties, expense of litigation, possible adverse publicity and *the possible generation of other claims are just a few things that come to mind which might encourage settlement offers but bear no relevant relationship to the awarding of punitive damages.* Considering the underlying policy behind the granting of punitive damages, that is punishment and deterrence, *we think the rule adopted by the Oregon court is the better approach to the issue.* Absent unusual circumstances, not shown in this case, we hold settlement offers and negotiations are inadmissible in evidence even when offered for the limited purpose of defending against an award of punitive damages."

Id., 665 P.2d at 743 (emphasis added). Of particular relevance to our case is the court's quotation from the Oregon case referred to above:

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excessive. The case was remanded for the district court to order an appropriate remittitur or, if unacceptable to plaintiff, a new trial.

> "*Evidence of the parties' conduct subsequent to the event,* which produces plaintiff's claim for punitive damages, whether aggravating or mitigating, *must be probative of the defendant's state of mind at the time of the transaction.* [Citation omitted.]
>
> . . . .
>
> "In the case here at issue the evidence of contrition and a conciliatory attitude of one of defendant's agents after the complaint was filed has scant relevance respecting the state of mind of other agents of defendant at the time [of the injury-causing event]. Assuming the evidence established the good faith and good will of defendant's president toward plaintiff, such conduct came as a response to the complaint, which prayed for substantial punitive damages. The evidence shows a desire to 'buy peace' and minimize the risk of an award of punitive damages and not that defendant dealt in good faith with plaintiff [at the time of the act complained of]."

Id., 665 P.2d at 741 (quoting *Byers v. Santiam Ford, Inc.*, 281 Or. 411, 416-17, 574 P.2d 1122, 1125 (1978), and adding emphasis).

We also find instructive the case of *Ford v. Guarantee Abstract & Title Co.*, 220 Kan. 244, 553 P.2d 254, 276-77 (1976), which is factually analogous to the instant case. In *Ford*, the trial court initially approved an award of punitive damages and then remitted a large portion of the award apparently upon learning after post-trial motions of an indemnification agreement affecting payment of the award. The Kansas Supreme Court held that the trial court erred in basing its remittitur on matters outside the record. "The court is not privileged to go beyond the issues in the case and make any determination whatsoever on matters outside of those issues." [9] *Id.*, 553 P.2d at 277.

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[9] In *Ford*, the Kansas Supreme Court concluded, after reviewing the facts and circumstances presented by the record, that a remittitur was warranted on appeal.

In sum, we conclude that because the post-trial conduct upon which the trial court relied in ordering remittitur in this case had no relevance to the injurious conduct underlying the claim for punitive damages, the court was without authority under either state or federal law to reduce the award on that basis. In addition, we are compelled to point out that the court's order subverts the goals of punishment and deterrence that underlie the assessment of punitive damages in Kansas. Far from punishing Playtex, the trial court here rewarded the company for continuing its tortious conduct long enough to use it as a bargaining chip in the remittitur proceedings. *See* Note, *Civil Procedure—Remittitur of Punitive Damages in Exchange for Product Recall—O'Gilvie v. International Playtex*, 34 Kan.L.Rev. 823, 836 (1986). The possibility that other potential defendants would be able to reduce their liability for punitive damages in the same way would encourage them to pursue the very behavior that the punitive award here was intended to deter, and thus would discourage voluntary cessation of injury-causing conduct. *See id.* at 838. Such a result is simply untenable.

V.

We have considered Playtex' remaining arguments and to the extent they have not been addressed by our discussions we find them without merit. The judgment against Playtex is affirmed. The order reducing the punitive damage award is reversed, and the case is remanded to the trial court with instruction to reinstate the judgment in accordance with the jury verdict.

SETH, Circuit Judge, dissenting:

I must respectfully dissent from the position taken by the majority and their characterization of the case. This case is really a medical malpractice case in strict liability clothing. The record demonstrates that the decedent had

a good layperson's knowledge of toxic shock syndrome ("TSS") and its symptoms, she knew of the warnings on the Playtex box, she thought she had symptoms of TSS and went to the doctor to ask about TSS.

The experts, even the doctor she consulted, agreed that if the diagnosis had been correct and she had then received treatment she would have survived. The warnings on the box with what she knew got her to the doctor which should have been the right place. This is what the warnings were for but the failure was the diagnosis—scarlet fever. This destroyed everything. When she later became seriously ill with a very high fever the doctor over the phone prescribed aspirin and water and the delay continued until it was too late.

This case cannot serve as a precedent for a products liability action because it is not such a case and is instead, as mentioned, a medical malpractice case. I would reverse and remand for a new trial for the following reasons.

The uncontested facts are that during her menstrual period in late March 1983, Mrs. O'Gilvie developed a sore throat, a red sunburn-type rash, a high fever, and diarrhea. These ailments are symptomatic of TSS, as well as various other diseases.

Decedent's husband testified that his wife first told him that she was not feeling well on the morning of Wednesday, March 30, 1983. Decedent's friend and classmate at a local school testified that on the way to class on Tuesday, March 29, Mrs. O'Gilvie complained that she had had a sore throat "all weekend" and a vaginal yeast infection.

On the morning of March 30, decedent made an appointment with her physician, Dr. Hays, a family practitioner in Wichita. Before the appointment Mrs. O'Gilvie read a TSS warning brochure from a package of Playtex tampons. Mrs. O'Gilvie's sister, who drove her to the

doctor's office, also read the warning insert. The sister testified:

> "[Betty] had a flyer that has the warning on it and that's why she was going to ask the doctor about the toxic shock because if you read the flyer, it shows that vomiting, diarrhea, rash, temperature, is all what could be classified as toxic shock and I read that."

During the drive to the doctor's office decedent discussed her concern about TSS with her sister. On a prior occasion, Mrs. O'Gilvie's mother-in-law, Mrs. Hunt, had talked with Mrs. O'Gilvie about TSS and had given her an article on the subject.

During the doctor's appointment, Mrs. O'Gilvie specifically asked about the possibility of TSS. Dr. Hays advised her that, "I did not think that was a thing to be concerned about," and diagnosed her condition as scarlet fever and a vaginal yeast infection. He prescribed a penicillin-based antibiotic that was appropriate for scarlet fever but not effective against TSS.

On her way home from Dr. Hays' office, Mrs. O'Gilvie asked her sister for a tampon, and her sister supplied a Kotex product. That afternoon, Mrs. O'Gilvie's symptoms continued and by 10:00 p.m. on March 30 her temperature had climbed to 105°. Alarmed, her husband called Dr. Hays at home and was advised by the doctor to administer aspirin and water and continue the antibiotics. Mr. O'Gilvie also called his mother, Mrs. Hunt, who came to the O'Gilvie home to attend her daughter-in-law during the night of March 30 and the morning and afternoon of March 31.

At around 9:00 a.m. on the morning of March 31, Mrs. Hunt telephoned Dr. Hays' office to report that Mrs. O'Gilvie's symptoms were not relieved. She spoke with a nurse, who advised continuing the prescribed treatment. At around 11:00 a.m. Mrs. Hunt supplied a Tampax

tampon to Mrs. O'Gilvie. Early that afternoon, Mrs. Hunt noticed Mrs. O'Gilvie's condition was deteriorating: her fingers appeared bluish and she was having difficulty speaking. Mrs. Hunt telephoned the doctor's office at around 2:00 p.m. and rushed Mrs. O'Gilvie there, where the nursing staff began emergency treatment and telephoned Dr. Hays at his home. Mrs. O'Gilvie was then transported to a Wichita hospital where Dr. Hays met her and diagnosed her condition as either TSS or a massive infection. He called for consultations by infectious disease, cardiac, and renal specialists, but treatment was not successful. On April 2, 1983, Mrs. O'Gilvie died. The cause of death listed on the hospital records was TSS.

On the day after Mrs. O'Gilvie's funeral, her friend and school classmate went to the O'Gilvie home to assist with some housekeeping chores. The friend testified that in the course of housecleaning, she found a box of Playtex tampons under the bathroom sink. The classmate also testified that during February 1983, she had seen the decedent purchase a box of Playtex tampons at a local supermarket. Mr. O'Gilvie testified that his wife customarily used Playtex sanitary products. Decedent's sister, however, testified that she routinely shopped for the O'Gilvie family at a nearby military base using her PX privileges and that during these shopping trips she purchased Kotex products exclusively for Mrs. O'Gilvie. Shortly after Mrs. O'Gilvie died, a Playtex tampon was found in her purse. Playtex International was the only named defendant and the only tampon manufacturer mentioned in the special interrogatories to the jury.

Although the etiology and kinetics of TSS are subjects of scientific debate and disagreement, there is a recognized association between the use of tampons and the onset of toxic shock syndrome. TSS-producing toxins are emitted by staphylococcus-aureus bacteria that have been found to multiply in numerous brands of catamenial products, including those manufactured by Playtex, Kotex and

Tampax. The toxins elaborated in the bacterial colonies have the capability of entering, infecting and ultimately poisoning the patient's system within the span of a few days.

The case was submitted to the jury on theories of strict tort liability for manufacturing a defective product; strict liability for inadequate warnings; negligent failure to warn; negligent failure to test the product; and negligent design.

Playtex tendered instructions on comparative fault and assumption of risk and contributory negligence. The proposed instructions included a directive to the jury that "[t]he parties to whom you have the discretion to assign fault are: Betty O'Gilvie, Dr. Hays (or his agents or employees), International Playtex, Inc., [o]ther tampon manufacturers."

The court denied Playtex's requested instructions on decedent's comparative fault and also rejected the defense of comparative negligence and assumption of risk. Instead, the court gave Instruction 23 concerning the defendent's conduct:

> "As indicated, the defendant has denied each of the plaintiff's contentions and further contends that Betty O'Gilvie was, in whole, or in part, causally responsible for the injuries and damages to herself and her family.
>
> "While a consumer has a duty to use ordinary care for her own safety and protection, because of the instincts of self-preservation and love of life, it is presumed here that the deceased, Betty O'Gilvie, at the time of the alleged use of defendant's product, was exercising requisite care to avoid any injury. In the Court's view, no evidence has been offered to overcome this presumption, and the issue of the decedent's negligent conduct, if any, is not before you.

> Additionally, it is the Court's finding that the doctrine of assumption of risk is not applicable in this case. Accordingly, the conduct of Betty O'Gilvie is not before you."

R.1:137.)

The court also refused to instruct the jury on the comparative fault or causation of other tampon manufacturers, specifically Kotex and Tampax. As for the Tampax product, the court reviewed the medical testimony and concluded that by the time decedent used it on the morning of March 31, her condition was probably irreversible. Regarding Kotex, the court observed that no evidence connected that product with Mrs. O'Gilvie's TSS.

Defendant objected to the omission of comparative causation and assumption of risk instructions and to the court's Instruction 23. Playtex also objected to the omission of other tampon manufacturers on the verdict form. At the close of plaintiffs' evidence Playtex had moved for a directed verdict on grounds, inter alia, that "there [was] no proof that Betty O'Gilvie used defendant's product in March, 1983."

The jury awarded a total of $250,000 to Mrs. O'Gilvie's estate for the decedent's pain and suffering; $1.25 million to Mrs. O'Gilvie's survivors as compensatory damages; and $10 million in punitive damages. The percentage of causation was allocated 20% to Dr. Hays and 80% to Playtex. Judgment was entered on these amounts, but the district court subsequently granted a partial remittitur of the punitive damages, based on the defendant's posttrial remedial conduct. 609 F.Supp. 817 (D.Kan.). Plaintiff appeals from the remittitur of punitive damages.

Playtex filed a motion for new trial or judgment notwithstanding the verdict, based on the court's exclusion of comparative fault instructions concerning Mrs. O'Gilvie's conduct and other tampon manufacturers. These

contentions are central to defendant's cross-appeal. Playtex also maintains that the court's instructions and comments about Playtex's toxic shock warnings misled the jury and that the evidence was insufficient to support punitive damages.

The Kansas legislature abolished contributory negligence as a bar to recovery in civil actions and adopted a modified form of comparative causation, sometimes called comparative fault, under which liability is allocated "in the proportion that the amount of his or her causal negligence bears to the amount of the causal negligence attributed to all parties against whom such recovery is allowed." Kan.Stat.Ann. § 60-258a(d). *See also Kennedy v. City of Sawyer*, 228 Kan. 439, 618 P.2d 788 (1980).

The doctrine of comparative causation or comparative fault applies under Kansas products liability law to both strict liability and implied warranty claims. *Kennedy v. City of Sawyer*, 228 Kan. 439, 618 P.2d 788 (1980). It also applies to all degrees and types of fault. *Hardin v. Manitowoc-Forsythe Corp.*, 691 F.2d 449 (10th Cir. 1982).

A touchstone of comparative causation is that "all parties to an occurrence must have their fault determined in one action, even though some parties cannot be formally joined or held legally responsible." *Albertson v. Volkswagenwerk Aktiengesellschaft*, 230 Kan. 368, 634 P.2d 1127, 1132 (1981). Even if a plaintiff has not formally joined a person or entity whose causal conduct may have contributed to the damages, the district court, in *Travelers Insurance Companies v. Jackson Communications Corp.*, 573 F.Supp. 1139, 1141 (D.Kan.1983), said: "[T]he absent tort-feasor's negligence may nevertheless be compared. Those who are not defendants but whose liability is compared are called 'phantom' parties. *Baird v. Phillips Petroleum Co.*, 535 F.Supp. 1371, 1378 (D. Kan.1982)."

During the trial, the parties and the district court referred to comparative causation and assumption of risk interchangeably. In *Hardin v. Manitowoc-Forsythe Corp.*, 691 F.2d 449, 454 n.4 (10th Cir. 1982), we observed that under Kansas' comparative causation doctrine:

> "[P]laintiff's fault must be compared with that of defendant whether it be characterized as contributory negligence, assumption of risk, product misuse, or unreasonable use. These defenses all depend on the reasonableness of plaintiff's conduct, a negligence concept."

Our decision in *Prince v. Leesona Corp.*, 720 F.2d 1166 (10th Cir. 1983), a Kansas strict products liability case, referred to the assumption of risk defense under Kansas law. *Prince* and *Hardin v. Manitowoc-Forsythe* both explain that the assumed risk doctrine was merely a means of permitting a jury to do what now it is required to do under comparative causation, thus to determine whether a consumer's conduct departed from the appropriate standard of care. The purpose of the comparative causation statute is to allow the jury to assess the reasonableness of the causal conduct and apportion liability accordingly. As we stated in *Palmer v. Ford Motor Co.*, 498 F.2d 952, 953 (10th Cir.1974), a products liability case under Kansas law: "The controlling factor is causation. . . . The labelling of the defense as contributory negligence or as assumption of risk is not determinative."

The primary focus of comparative causation analysis under Kansas law is thus on the duties which each party bears to the others. *Hardin v. Manitowoc-Forsythe*, 691 F.2dat 455 n.5. In *Prince v. Leesona Corp.*, 720 F.2d 1166, at 1171, we said:

> "In essence, what Kansas has done is to let the jury determine the degree to which each actor has departed from his or her respective duty and apportion fault accordingly. As explained in *Kennedy*, all types

> of fault, regardless of degree, are to be compared with that of defendant whether the fault is characterized as contributory negligence, assumption of risk, product misuse, or unreasonable use. All of these defenses depend on the reasonableness of plaintiff's conduct, a negligence concept." (Footnote omitted.)

In order to compare causation under Kansas law the jury must be allowed to consider the doctrine as to all participants in the related series of events all within the sufficiency of the evidence strictures.

The possibility that the user would be mis-diagnosed does not negate the possibility that the jury could have found plaintiff's own conduct unreasonable, either in continuing to use the tampons or in delaying her visit to the doctor.

The facts surrounding the O'Gilvie claims are markedly different from the situation presented in *Wooderson v. Ortho Pharmaceutical Corp.*, 235 Kan. 387, 681 P.2d 1038 (1984). *Wooderson* was a failure-to-warn case where the defendant pharmaceutical manufacturer asserted that the plaintiff's negligent use of the product and her three-day delay in the course of medical treatment were contributing causes of her injury. The expert testimony in *Wooderson* indicated that plaintiff, who had been ingesting defendant's product for several years, had suffered cumulative long-term blood vessel deterioration. The trial court refused to give a comparative causation instruction regarding the plaintiff's conduct and the Kansas Supreme Court affirmed because there was no evidence that plaintiff's three-day delay could have caused the disaster. Here, on the other hand, a three-day difference apparently was crucial, given the short-term cycle of TSS. Thus "[t]he question of causation . . . is one for resolution by the jury in the absence of conclusive proof that makes only one result possible." *Palmer*, 498 F.2d at 953.

Where the plaintiff's own conduct caused or partially caused his or her injury planitiff's responsibility and reasonableness must be compared with the conduct of other participants. *Lenherr v. NRM Corp.*, 504 F.Supp. 165, 175 (D.Kan.1980); *Brown v. Keill*, 224 Kan. 195, 580 P.2d 867, 875-76 (1978). Kansas courts have found error in the refusal of a comparative fault instruction which did not include the consideration of all potentially culpable participants. *McCart v. Muir*, 230 Kan. 618, 641 P.2d 384, 388-89 (1982).

The instructions in the case before us specifically excluded consideration of questions of causation posed by plaintiff's own conduct. Those questions properly lay within the province of the jury as did the questions as to causation arising from decedent's use of other products. *Pape v. Kansas Power and Light Co.*, 231 Kan. 441, 647 P.2d 320 (1982); *McCart v. Muir*, 230 Kan. 618, 641 P.2d 384 (1982).

Regarding the "phantom defendants," Kotex and Tampax, expert testimony varied as to when Mrs. O'Gilvie's condition became irreversible, and a jury question arose. The evidence did not conclusively establish whether Mrs. O'Gilvie's condition was affected by the Kotex or Tampax products that were supplied to her on March 30 and 31 and before. Nevertheless, the evidence that those products were used by the decedent during a critical time and the possibility that they could have been associated with her TSS necessitated the submission of the issue of comparative causation of the phantom defendants to the jury. This was not done as the special interrogatories only asked whether Mrs. O'Gilvie used Playtex tampons, without mentioning any other brands, and whether the Playtex product caused or contributed to her development of TSS. Although TSS toxins may remain in the bloodstream or organs, Dr. Hays testified that once a tampon is removed the site of toxin-producing bacteria is also removed. When a new tampon is inserted it presents a

new possibility for staphylococcus bacteria to colonize. Some of the expert testimony supported this theory, although other testimony indicated that progressive, cumulative toxemia may have been completed in Mrs. O'Gilvie's case by the time on March 31 that the Tampax product was used. Yet another expert witness, a research microbiologist, recounted an experiment performed in August 1983, indicating that Playtex tampons appeared to contain a substance inhibiting the growth of staphylococcus-aureus bacteria. The jury should have been allowed to weigh the testimony and consider whether the Kotex or Tampax products contributed to the decedent's condition. The district court acknowledged that the onset of TSS—before or after use of the Kotex or Tampax tampons—was a complicated question.

Pursuant to FDA regulations that became effective in 1982, Playtex tampon packages bore the notice: "Attention: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information." (R.10:145.) The warning brochure included with the Playtex product in part stated in very large type:

> "IMPORTANT INFORMATION ABOUT TOXIC SHOCK SYNDROME (TSS)"

And stated in smaller block type:

> "READ AND SAVE THIS INFORMATION ABOUT THESE TAMPONS:
>
> "*WARNING SIGNS*
>
> "WARNING SIGNS OF TSS FOR EXAMPLE ARE: SUDDEN FEVER (USUALLY 102° OR MORE) AND VOMITING, DIARRHEA, FAINTING OR NEAR FAINTING WHEN STANDING UP, DIZZINESS, OR A RASH THAT LOOKS LIKE A SUNBURN.

> "IF THESE OR OTHER SIGNS OF TSS APPEAR, YOU SHOULD REMOVE THE TAMPON AT ONCE, DISCONTINUE USE, AND SEE YOUR DOCTOR IMMEDIATELY."

Further in small type:

> "There is a risk of TSS to all women using tampons during their menstrual period. TSS is a rare but serious disease that may cause death. The reported risks are higher to women under 30. . . . "You can avoid any possible risk of getting tampon-associated TSS by not using tampons. . . ."

One of the most significant aspects of this case is what prompted the decedent to visit her doctor when she became ill on March 29 or 30, and her awareness at that time of the risk of TSS to the users of tampons. The record shows that she had some prior knowledge of the relationship of the use of tampons with TSS and the risk involved. She had also read the warning on the Playtex enclosure and box and was concerned that she might have TSS. Her concern moved her to see her doctor. She thus asked her sister to drive her to Dr. Hays' office. She told her sister, as mentioned, that she was going to ask the doctor if she had TSS. She said that she had read a pamphlet which indicated her symptoms were like those of TSS. The decedent did see her doctor on that day. She asked him whether she had TSS and about tampon use and TSS.

Thus the record demonstrates that the decedent was aware of the risks associated with the use of tampons; that she knew what the symptoms of TSS were; that the symptoms she had on March 30 were similar to those of TSS; that this similarity was such that she wanted to see the doctor and ask whether she had TSS. This she did. Thus her visit to the doctor must be taken as decedent's response to her symptoms in the context of what she knew about tampons and TSS. This knowledge included

what her mother-in-law provided and the warnings on the Playtex box. Her reaction was right. Her suspicions as to her symptoms were correct and her actions should have been effective. The information she had and the warnings had served a purpose. However, she continued to use tampons during this short but critical period before she saw the doctor despite her concern that she might have TSS and the warning on the box or pamphlet to stop using tampons under such circumstances. With decedent's visit to Dr. Hays' office the proof moved from one significant segment of the case to another. Her responses to her symptoms and knowledge had gotten her there. The doctor was then to provide an answer to her worries. In response to her concern, her questions about TSS, and her symptoms, Dr. Hays told her she had scarlet fever. The decedent continued thereafter to use tampons but apparently not those of defendant.

The doctors who testified were all of the opinion that had the decedent been treated for TSS when she first saw Dr. Hays, or at least had then been hospitalized, she probably would have survived. This was also the opinion of Dr. Hays. Dr. Hays maintained throughout his testimony that Mrs. O'Gilvie had scarlet fever at the time of her appointment on March 30 and developed TSS on the afternoon of March 31 when her fingers turned blue.

The record is not altogether clear as to when the decedent read the warning on the Playtex package and folder in the package. However, as mentioned, it was shortly before she went to see the doctor and probably on the second day that she felt ill—the 30th. It was at a time, according to the doctors who testified, when she probably would have survived had she received a correct diagnosis and treatment. The misdiagnosis destroyed the effectiveness of the warnings here in evidence.

The use of tampons by the decedent after her concern that she had TSS introduced an element and degree of

causation by the decedent which, under Kansas law, must be evaluated by the jury as herein described. This was not done at trial as the trial judge instructed the jury that causation by the decedent was not its concern. Thus the trial court observed, and included in Instruction No. 23, a statement that Mrs. O'Gilvie's "fault" should not be considered by the jury as the defendant had failed to rebut the presumption of due care attributed to a decedent under these circumstances. This was in substance a directed verdict for the plaintiff as to her comparative fault under the statute. As to the presumption of care attributed to the decedent, the Kansas court in *Akin v. Estate of Hill*, 201 Kan. 306, 440 P.2d 585, 588, observed that "[t]his presumption yields . . . to direct controverting evidence." The record before us contains such evidence as herein described.

The measure for comparative causation under Kansas products liability law is the degree to which an injured consumer departed from his or her duty of ordinary care. Accordingly, the jury should be given the opportunity to assess decedent's conduct as to causation and reasonableness. The jury should be allowed to examine the causation, if any, by the "phantom defendants" Kotex and Tampax as well.

I would reverse the judgment of the district court and remand for a new trial.

APPENDIX B

UNITED STATES DISTRICT COURT
D. KANSAS

No. 83-1846-K

KELLY M. O'GILVIE, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF BETTY L. O'GILVIE, DECEASED; AND STEPHANIE L. O'GILVIE, A MINOR, AND KEVIN M. O'GILVIE, A MINOR, BY AND THROUGH KELLY M. O'GILVIE, THEIR FATHER AND NATURAL GUARDIAN,
Plaintiffs,

v.

INTERNATIONAL PLAYTEX, INC., A CORPORATION,
Defendant.

May 24, 1985

Gerald L. Michaud and Mark B. Hutton, Wichita, Kan., for plaintiffs.

Larry Wall, Fleeson, Gooing, Coulson & Kitch, Wichita, Kan., Charles M. McCaghey, Olwine, Connelly, Chase, O'Donnell & Weyner, New York City, for defendant.

REMITTITUR OF PUNITIVE DAMAGES

PATRICK F. KELLY, District Judge.

On February 25, 1985, the jury unanimously responded to certain questions propounded by the Court as follows:

> 1. Was decedent Betty O'Gilvie, in late March 1983 and during the course of her mestrual cycle, using defendant's product?
>
> Yes × No

2. In March 1983, did use of Playtex super deodorant tampons cause or contribute to the cause of toxic shock syndrome?

Yes × No

3. As compared to all other tampons, including competitors, is there an increased risk of contracting toxic shock syndrome when using these super deodorant tampons?

Yes × No

4. Did the label and instructions inside and outside the Playtex box at the time the product was being used by Betty O'Gilvie adequately and fairly inform and warn Betty O'Gilvie of the risk of TSS which may be fatal from using Playtex tampons?

Yes No ×

5. Do you find International Playtex and/or Dr. Thomas Hays to be at fault in this case?

Yes × No

6. If you answer No. 5 "yes", then, considering all of the fault at 100%, what percentage of fault is attributable to each of the following:

International Playtex	(0 to 100%)	80%
Dr. Hays (and his agents or employees)	(0 to 100%)	20%
Total		100%

7. Without considering the percentage of fault found in No. 6, what total amount of damages do you find should be awarded:

Conscious pain and suffering of Betty O'Gilvie	$250,000.00
Nonpecuniary loss (not to exceed $25,000) to Kelly O'Gilvie and children	25,000.00
Pecuniary loss to Kelly O'Gilvie and children	1,250,000.00

8. Did International Playtex know, or should it have known, of the increased risk of developing toxic

shock syndrome when using Playtex super deodorant tampons at the time of the death of Betty O'Gilvie?

Yes × No

9. Was the failure of International Playtex to adequately warn about the increased risk of toxic shock syndrome with the usage of Playtex super deodorant tampons a reckless disregard by International Playtex of the consequences of its acts?

Yes × No

10. If your answer to No. 9 is "yes", you may assess punitive damages as you feel are warranted from the evidence.

Punitive damages	$10 million

On March 21, 1985, the Court took up defendant's motions, all of which were overruled. Specifically, the jury's assessment of punitive damages, while substantial, was found to be not excessive, nor did it shock the Court's conscience. In the Court's view, in light of the evidence and the jury's findings, the jurors expressed their "outrage" the only way they could— with money damages. Conversely, the jurors were actually saying, "Take that damnable product off the market!"

Following the Court's findings and rulings, the Court tendered a provocative proposition to the defendant. Speaking indirectly to the President of Beatrice Company, the parent company of defendant International Playtex, the Court commented in substance as follows:

> That this person should know, that in the Court's view, there was ample evidence to support each finding of the jury; that punitive damages are essentially intended to deter wrongdoing; that in the event there are no changes contemplated by the defendant International Playtex, such damages as manifested by *this* jury are probably "only the beginning. There surely will be others!"

Further, the Court ventured that the President of Beatrice was probably an entirely decent person, and if he concurred with these findings, he would surely order a change.

The Court then represented to defendant's counsel that in the event this person, or his authorized representative, elected to appear in this Court on April 29, 1985, to acknowledge the jury's findings as factually established and announce the removal of the polyacrylate tampon from the marketplace, the Court in turn would consider a substantial reduction, if not elimination, of the punitive damages award.

The Court's tender of a reduction of any portion of the jury verdict on the basis of the conditions set forth was probably without precedent. This proposition was an innovative remedy geared to what the Court reasoned as "that which ought to be." In this, the Court was drawn from similar experiences in dealing with those persons who have appeared here for the purposes of punishment. In many instances the ordeal itself is punishment enough. In others, deterrence is paramount. When wrongdoing is acknowledged, where changed [sic] is agreed to, indeed, where change has occurred, the Court is usually impressed and persuaded principally as to what further punishment, if any, is then in order. In the Court's view, such remedial events are appropriate elements of mitigation which, in the Court's discretion, should be noted and considered.

Within two weeks of that hearing, the Court noted the defendant's public announcement to the effect that its Playtex Slender, Super and Super Plus Tampons—those containing polyacrylate fibers—will no longer be made. Shortly thereafter, defendant's counsel communicated with the Court in the interest of further conference and for a continuance of the pending hearing. With the concurrence of plaintiffs' counsel, the Court conferred with counsel for International Playtex; the hearing was set over to May 24, 1985.

At the outset, the defendant's counsel were apprised that it has never been the Court's intention to negotiate or otherwise dictate the course of defendant's decisions. Indeed, whatever decisions were made by the defendant company, were its alone to make.

In the course of the first session, the defendant's counsel specifically represented that the defendant had indeed removed polyacrylate fibers from all tampons, and all tampons with polyacrylate fibers are being removed from the market. The Court discussed the present state of the warning on defendant's product which acknowledges an "association" between the use of the tampon and toxic shock syndrome (TSS). The jury found that this warning was inadequate and the Court concurs. Additionally, the Court took up the necessity of a broad-spread communication by the industry to the consuming public and the medical community with regard to early signs and symptoms of TSS.

As to the need for a public education program, the defendant's counsel have outlined a meaningful program which, given time and exposure, should serve to inform and alert the public and medical community about the toxic shock process.

With regard to the warning, defendant's counsel have represented to the Court that as of now the defendant's alert statement or any warnings with regard to the sale of any tampon will be modified to include the following:

> There are scientific studies which have concluded that tampons contribute to the cause of TSS.

While some may argue as to the adequacy of this statement, all should agree that it represents a sizeable "first step." Indeed, the Court is the first to note the sense of sincerity exercised by defendant's counsel. The Court is ever sensitive to certain pragmatics of this action. Given misperception, it could surely be abused by some, either in the course of pending litigation here or

elsewhere—and in future days! However unfortunate, it may well invite additional litigation. From the Court's perspective, however, the defendant's action represents a commendable exercise of fortitude and decency.

Of paramount importance, the Court finds that such action is a significant post-judgment remedial and mitigatory response to the jury's findings. Indeed, the jury's intent has been substantially sufficed. In view of the defendant's actions, the Court finds that the punitive damages award is now, in part, excessive and unnecessary. The jury's finding of ten million dollars ($10,000,000.00) is reduced to the amount of one million three hundred fifty thousand dollars ($1,350,000.00), effective from February 26, 1985. This remaining sum is intended to represent the jury's assessment regarding the element of punishment and is clearly the proprietary right of the plaintiffs. In the Court's view, such an amount is fair, reasonable and deserving. In light of defendant's action, the Court here asserts that International Playtex should not be called upon to respond in any punitive damage claims, at least with those matters pending here. It has faced its situation, it has acted most responsibly, and it has acted decently. It can be no further deterred; it has been punished enough!

Some comment is in order for the benefit of the plaintiff, Mr. Kelly O'Gilvie, for himself and on behalf of his children. Following the jury's verdict, they enjoyed the expectancy of a substantial recovery. Yet, they did not bring this action for personal enrichment. They sought punitive damages solely to punish and deter the defendant from future wrongdoing. In the face of defendant's announcements and representations, the plaintiffs have truly won!

Additionally, perhaps some solace is owing to plaintiffs' counsel. These lawyers, doubtless, have proceeded here with an attorney fee arrangement contingent upon the amount of recovery. This procedure is entirely ac-

ceptable and understood. They have surely advanced substantial expenses necessary for the successful trial of this case. To reduce the recovery reduces their expectancy. Fortunately, trial of this case involves the kinds of lawyers with whom the Court can find comfort in open discussions.

The Court is first to note that it is only through these attorneys' considerable efforts, their commitment of much time in study and preparation, and their skills in the trial of this case, that plaintiffs have prevailed. Not every lawyer would share this experience. In the Court's view, however, they are also the kinds of lawyers who quietly share a certain professional satisfaction and sense of pride in seeing our adversary system work. Their efforts here have literally changed an industry! In the minds of good lawyers such as these, no amount of recompense quite touches that accomplishment. To them, the Court suggests that there will be other cases and other conquests. Indeed, attorneys such as these are always welcome here.

IT IS THEREFORE ORDERED this 24 day of May, 1985, that the jury's assessment of ten million dollars ($10,000,000.00) punitive damages is reduced to the sum of one million three hundred fifty thousand dollars ($1,350,000,000.00), effective from the date of first entry of judgment.

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

JULY TERM—September 24, 1987

Before Honorable William J. Holloway, Jr., Honorable Monroe G. McKay, Honorable James K. Logan, Honorable Stephanie K. Seymour, Honorable John P. Moore, Honorable Deanell R. Tacha, Honorable Bobby R. Baldock, and Honorable Oliver Seth, Circuit Judges.

Nos. 85-1861 and 85-1887

KELLY M. O'GILVIE, individually and as Administrator of the Estate of Betty L. O'Gilvie, deceased; and STEPHANIE L. O'GILVIE, a minor, and KELVIN M. O'GILVIE, a minor, by and through Kelly M. O'Gilvie, their father and natural guardian,

Plaintiffs-Appellants,
Cross-Appellees,

vs.

INTERNATIONAL PLAYTEX, INC.,
Defendant-Appellee,
Cross-Appellant,

MOTOR VEHICLE MANUFACTURERS ASSOCIATION, INC., PRODUCT LIABILITY ADVISORY COUNCIL, INC., and GULF & GREAT PLAINS LEGAL FOUNDATION,
Amici Curiae.

This matter comes on for consideration of defendant-Appellee/cross-appellant's petition for rehearing and suggestion for rehearing en banc.

The petition for rehearing is denied by the panel who decided the appeal on the merits. The suggestion for rehearing en banc having failed to receive the votes of a majority of the judges of the court in regular active service is also denied. Judges Moore, Tacha and Baldock would grant rehearing en banc.

Judge Steven A. Anderson took no part in consideration of the suggestion for rehearing en banc.

ROBERT L. HOECKER
Clerk

By: /s/ Patrick Fisher
PATRICK FISHER
Chief Deputy Clerk

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

SEPTEMBER TERM—October 13, 1987

Before the Honorable Monroe G. McKay, Honorable Oliver Seth and Honorable Stephanie K. Seymour, Circuit Judges.

Nos. 85-1861 and 85-1887

KELLY M. O'GILVIE, individually and as Administrator of the Estate of Betty L. O'Gilvie, deceased; and STEPHANIE L. O'GILVIE, a minor, and KELVIN M. O'GILVIE, a minor, by and through Kelly M. O'Gilvie, their father and natural guardian,

Plaintiffs-Appellants,

vs.

INTERNATIONAL PLAYTEX, INCORPORATED,
Defendant-Appellee,

MOTOR VEHICLE MANUFACTURERS ASSOCIATION, INC., PRODUCT LIABILITY ADVISORY COUNCIL, INC., and GULF & GREAT PLAINS LEGAL FOUNDATION,
Amici Curiae

This matter comes on for consideration of the motion for stay of mandate filed in the captioned cause by Appellee, International Playtex, Incorporated.

Upon consideration whereof the motion for stay of mandate is granted. It is ordered that the mandate is stayed to and including December 31, 1987, pending certiorari and that if, on or before that date there is filed with the Clerk of the Court of Appeals a notice from the Clerk of the Supreme Court of the United States that a petition for writ of certiorari has been timely filed in the Supreme Court, the stay shall continue until final disposition by the Supreme Court.

/s/ Robert L. Hoecker
ROBERT L. HOECKER
Clerk

APPENDIX E

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

No. 83-1846-K

KELLY M. O'GILVIE, individually and as Administrator of the Estate of Betty L. O'Gilvie, deceased; and STEPHANIE L. O'GILVIE, a minor, and KELVIN M. O'GILVIE, a minor, by and through Kelly M. O'Gilvie, their father and natural guardian,

Plaintiffs,

vs.

INTERNATIONAL PLAYTEX, INC., a Corporation,

Defendant.

[Filed Feb. 26, 1985]

INSTRUCTIONS TO THE JURY

(Honorable Patrick F. Kelly Presiding)

INSTRUCTION NO. 14

The Court has taken note of certain rulings of the Food and Drug Administration and has concluded that the warnings on the label of defendant's product and the alert statement contained within the package are in conformity with these regulations.

APPENDIX F

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

No. 83-1846-K

KELLY M. O'GILVIE, individually and as Administrator of the Estate of Betty L. O'Gilvie, deceased; and STEPHANIE L. O'GILVIE, a minor, and KELVIN M. O'GILVIE, a minor, by and through Kelly M. O'Gilvie, their father and natural guardian,

Plaintiffs,

INTERNATIONAL PLAYTEX, INC., *a Corporation,*
Defendant.

VERDICT

We, the jury, being duly impaneled, do make the following answers to the questions propounded by the Court:

1. Was decedent Betty O'Gilvie, in late March 1983 and during the course of her menstrual cycle, using defendant's product?

Yes × No

[If your answer to No. 1 is "no", please have your foreperson date and sign the verdict form and return to the courtroom. If your answer is "yes", proceed to the next question.]

2. In March 1983, did use of Playtex super deodorant tampons cause or contribute to the cause of toxic shock syndrome?

Yes × No

[If your answer to No. 2 is "no", please have your foreperson date and sign the verdict form and return to the courtroom. If your answer is "yes", proceed to the next question.]

3. As compared to all other tampons, including competitors, is there an increased risk of contracting toxic shock syndrome when using these super deodorant tampons?

Yes × No

4. Did the label and instructions inside and outside the Playtex box at the time the product was being used by Betty O'Gilvie adequately and fairly inform and warn Betty O'Gilvie of the risk of TSS which may be fatal from using Playtex tampons?

Yes No ×

[If your answer to No. 4 is "yes", please have your foreperson date and sign the verdict form and return to the courtroom. If your answer is "no", proceed to the next question.]

5. Do you find International Playtex and/or Dr. Thomas Hays to be at fault in this case?

Yes × No

6. If you answer No. 5 "yes", then, considering all of the fault at 100%, what percentage of fault is attributable to each of the following:

International Playtex	(0 to 100%)	80%
Dr. Hays (and his agents or employees)	(0 to 100%)	20%
	Total	100%

7. Without considering the percentage of fault found in No. 6, what total amount of damages do you find should be awarded:

Conscious pain and suffering of Betty O'Gilvie	$250,000.00
Nonpecuniary loss (not to exceed $25,000.00 to Kelly O'Gilvie and children	$25,000.00
Pecuniary loss to Kelly O'Gilvie and children	1,250,000.00

[If you find in No. 3 above that there is an increased risk of developing toxic shock syndrome when using a super absorbent Playtex tampon, and if you found in No. 4 above that International Playtex failed to adequately and fairly inform and warn Betty O'Gilvie of this risk, then proceed to No. 8]

8. Did International Playtex know, or should it have known, of the increased risk of developing toxic shock syndrome when using Playtex super deodorant tampons at the time of the death of Betty O'Gilvie?

Yes × No

9. Was the failure of International Playtex to adequately warn about the increased risk of toxic shock syndrome with the usage of Playtex super deodorant tampons a reckless disregard by International Playtex of the consequences of its acts?

Yes × No

10. If your answer to No. 9 is "yes", you may assess punitive damages as you feel are warranted from the evidence.

Punitive damages	$10 million

2/25/85
Date

/s/ Jerry Hayes
JERRY HAYES
Foreperson

APPENDIX G

[3302]

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF KANSAS

Case No. 83-1845

Volume No. 36

KELLY M. O'GILVIE, *et al.*,
Plaintiffs,

vs.

INTERNATIONAL PLAYTEX, INC., A CORPORATION,
Defendant.

TRANSCRIPT OF JURY TRIAL

(Friday AM/PM Session.)

On the 22nd day of February 1985, came on to be heard the above-entitled and numbered cause, with a duly impanelled jury, before the HONORABLE PATRICK F. KELLY, Judge of the United States District Court for the District of Kansas, Sitting in Wichita.

APPEARANCES:

The Plaintiffs appeared by and through Gerald Michaud and Mark Hutton;

The Defendant appeared by and through Larry Wall, Charles McCaghey and Glen Pogust.

[3353] THE COURT: Which I thought we agreed was law.

MR. MICHAUD: I don't disagree with that; in other words, I think that the theories have been intermingled. I don't disagree with the Court but I do disagree with telling them that that unreasonably dangerous product can be made safe or all right if it is adequately warned. That's what I say about Number 12.

THE COURT: As to 12, and as to your suggestion about the inadequacy of the instruction, I think that instruction, coupled with the definition of a defect in 11, covers what it is you purport to claim, and it embodies that which is inherent in implied warranty in the strict liability theory. You're overruled.

MR. MICHAUD: Skipping 13, no comment.

Number 14, I object to the Court telling the jury that as a matter of fact the defendant has complied with the FDA regulations on warning.

THE COURT: All right. I can only say at this time as I understood the evidence, when the FDA findings were handed up and having studied the directive of of [sic] FDA as to warning and comparing them with the alert statement in evidence, I'm convinced that the company conformed with [3354] that regulation in the statement and the alert statement says what the warning requisite says and coincides with it, and if you will, Mr. Michaud, I thought at the time when this was taken up there was concurrence between the parties as to that. In any event, I don't believe there's anything for the jury to determine as to whether this defendant has, in fact, conformed with the requisites warning. Not a jury question.

MR. MICHAUD: I felt—and I concede, Your Honor, that I indicated to the Court and I do today agree that the package insert language is either identical to or the equivalent of that set out in the Federal Register. On the other hand, I don't agree that that complies with the rules and regulations and requirements. That is my objection.

THE COURT: Overruled. What else do you have?

MR. MICHAUD: I object to Instruction Number 25, Your Honor, not because you should not instruct, because I concede that I think you have to submit the negligence of Dr. Hays to this jury, and my problem with it is that some of the language in regard to the instruction—I'm trying to find exactly what it was when I read it. I guess I didn't underscore it. But Your Honor tells the jury that —all right. I object to Paragraph Number 2 and Paragraph 3, second page, 2 and 3 on the second page.

THE COURT: Should have had a physician and if the physician elects . . . .

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[3464]

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF KANSAS

Case No. 83-1846
Volume No. 37

KELLY O'GILVIE, *et al.*,
Plaintiffs,

vs.

INTERNATIONAL PLAYTEX,
Defendant.

POST-TRIAL MOTIONS AND COURT'S FINDINGS

On the 21st day of March, 1985, came on to be heard Post-Trial Motions and Rulings on the above-entitled and numbered cause before the HONORABLE PATRICK F. KELLY, Judge of the United States District Court for the District of Kansas, Sitting in Wichita.

APPEARANCES:

The Plaintiffs appeared by and through Gerald Michaud and Mark Hutton;

The Defendant appeared by and through Charles McCaghey, Larry Wall and Glen Pogust.

* * * *

[3519] THE COURT: Jury heard him and I don't think they cared much for Mr. Butensky as they listened to him. You did not address the very question I said was on the table in the discovery.

MR. McCAGHEY: Judge, that one question you said about putting numbers on absorbency, I mean, quite frankly all kinds of considerations are had by a company in facing these problems. Therefore, to take a consideration on his part as to what a company might do and turn

it into a deliberate act of wrongdoing, Your Honor, I think tries to find in extracts and spoken words out of context evidence to show wrongful evilness, and that's what punitive damage is and I don't think it's there, Your Honor, respectfully.

THE COURT: Talk about the amount of the verdict. Jury returned a verdict of ten million dollars. I have been informed since probably the largest punitive damage award in at least this district, this state and with which I'm acquainted. No question but what a substantial sum.

The test of punitive damages, seems to me, is it a sum sufficient to punish and/or deter them or others? I have often said it's to get their attention, to make it smart. I think I mentioned to you a little analogy at the time of this trial somewhere: Somebody would stand up and say why, whether it's a stockholder or perhaps the president of [3520] Beatrice, I don't know, but someone would be concerned and sufficient to change.

Now, with that said, you have said that it is criminal it's unconstitutional. I'm going to say before you start your argument that you should also know *Woodardson* was a seven million dollar punitive damage award approved by the Kansas Supreme Court. Tell me why ten million dollars—

MR. WALL: You have your numbers wrong.

MR. McCAGHEY: I think it was four million, Your Honor. Total award was four million, two million punitive.

THE COURT: I stand corrected.

MR. McCAGHEY: I'm not an expert on Kansas Law but I did read *Woodardson.*

THE COURT: Substantial dollars at least.

MR. McCAGHEY: Dollars are substantial. In that instance, as I recall it, there was a specific finding that there was no warning in the package inserts on that drug about a specific condition, and the Court said, based upon an omission of that sort, then the jury could consider punitive damages. I don't think anyone can suggest that about this warning.

THE COURT: I will ask you this: In the face of the the jury's verdict—I know you don't agree with it—but which says your product will likely cause toxic shock and kill people, content of your product even increases the risk, your [3521] warnings are inadequate, people with authority to do something about it know this or should know this and have done nothing, what do you say that verdict is saying to Playtex?

MR. McCAGHEY: Judge, I think the verdict is saying go on appeal to Playtex, Judge.

THE COURT: You don't think they are saying: Change your product?

MR. McCAGHEY: I'm not sure. Judge, I don't want to get into trying to figure out why the jury decided that. If we are talking about the ten million, Your Honor, I think the dollar amount shocks the conscience. You have a company here, Judge, that is using the same warnings as all of its competitors, warning approved by the FDA, no one suggesting the product should come off the market, no one has told this company what it should do now in terms of changing that product in the scientific community, Judge.

THE COURT: This jury verdict is saying, who heard the scientific community as clearly as you will ever hear if you try this case a dozen times, Mr. McCaghey, that you're wrong; this product causes toxic shock and your company knows it. That's what they said in that verdict by their answer, right?

MR. McCAGHEY: Judge, that may well be what they say but that jury might be wrong too after everything is said and done.

[3522] THE COURT: All right.

MR. McCAGHEY: In terms of the ten million dollars, I think it does shock the conscience. I think to subject a company to this type of punitive damage award which can be repeated one after another in cases across the land is wrong, I don't think it is justified. If you

ask me what dollar amount should it be, well, you know my ultimate answer to you is you need no dollars.

THE COURT: Should it be a sum that the company with the income and assets of Playtex would absorb as a cost of doing business and move on?

MR. McCAGHEY: Judge—

THE COURT: Or is it sum [sic] that makes this company say: We better listen. We better do something. We better change?

MR. McCAGHEY: Judge, this company is going to listen to what comes down by way of verdicts, et cetera, regardless of the sum. Now, I think you already have a sum in hand and—

THE COURT: I think the jury gave you a sum in hand that surely ought to say you better listen.

MR. McCAGHEY: I'm sure this company, Judge, will listen to this verdict regardless of what the dollar amounts of it are.

THE COURT: I wonder if they are listening to [3523] the extent that if I'm correct that you are collaterally estopped to raise again causation, we have five cases pending here with your company and punitive damages will continue to go to the jury until I hear you say you have got their attention. There has to come a time, Mr. McCaghey, when this company will listen, isn't there? What do you think this verdict is saying?

MR. McCAGHEY: Pardon me.

THE COURT: What do you think this verdict is saying? Is it saying: Change, stop what you're doing, you're killing people. Take the product off of the market. Is that what they are saying?

MR. McCAGHEY: May well be saying that to them. I'm not suggesting to you that it is not. You have to understand that I'm not in a position here where I'm going to concede to the validity of that verdict. I personally feel it is improper and I personally feel ten million dollars shocks the conscience and that it should be either done away with totally or there be a remittitur on it.

THE COURT: That's why we are here. I have given serious thought to it, Mr. McCaghey, and I'm the first to agree that it is a substantial sum, but I also accept this jury's verdict. This product does cause toxic shock and death, contents of your product, polyacrylate, does increase that risk, your warnings are inadequate, your company knows it, or [3524] should have known it, and has done nothing. Now what is it that is sufficient but to say that to [sic] know? Shouldn't be a sum that is accepted or absorbed as a cost of doing business. I think it ought to be enough that makes somebody with authority to change.

I think this jury's verdict is really saying: Playtex, take that damnable product off the market, you're killing people with it; it's inadequate in its warnings, change. I think it's saying: Go back to FDA and explain to them that we are ready to change, and that the FDA is wrong, they have not had what this jury heard. I think that's what they are saying with regard to the verdict.

If you will, as to this amount, it is a substantial sum. This jury heard something about Playtex Company, its assets and earnings. In my view and in light of their findings, as I understand it and accept it, there is nothing criminal or punitive nor unconstitutional about it. It is no more than the voice of this jury, voice of this community saying: Stop it. They weighed the enormity of the wrongdoing and that's what that verdict intends to say.

I have to say to you that the amount of the verdict does not bother me, nor shock my conscience, and in light of the findings this jury made I'm not surprised with it. I'm frank to say that I recall Mr. Michaud had asked to increase the prayer to twenty million dollars and I denied it for the [3525] reasons we took up, which also offended him. Had this gone to the jury for twenty million dollars, it would not have surprised me had they entered such a verdict and it also would stand.

With that said, this jury's verdict as to punitive damages will presently stand. It is the product of a fully tried case, well prepared by able counsel to a fair and impartial jury who heard it all, who understood the duty and performed, as I said to them as a I discharged them, superbly. They truly are the conscience of our community. They reached their decision and if I understand their answer, they had no other choice, and that verdict for this reason will not be touched by this Court.

Let me make an aside having said that to you: Punitive damages in the present state of our law, rightly or wrongly, is truly the only way the jury can express itself, if you will, to express its outrage or to attempt to communicate punishment or deterrence. I'm convinced, Mr. McCaghey, this jury is saying: Change. Take that polyacrylate rayon product off the market. It is killing people. It's increasing the risks of it, and your company knows it, and change.

As you and I both know this jury nor is this Court authorized to follow through with that. Certainly when I find that the verdict is not excessive, I have no real authority with which I'm aware to do anything. I can't order them to [3526] seize or desist, nor can I order an FDA hearing that would surely follow if they accepted this jury's verdict as I have heard it. If you will, others can.

If I were the plaintiffs' counsel, I would not have awaited to today to, first of all, put this jury's verdict in the hands of the president of Beatrice. Beatrice is a huge conglomerate and Playtex is an important profit center of Beatrice. It's also a responsible, consumer-oriented company. I'm sure the president didn't get there for any other reason than he is a very good businessman, and were he to understand that this is only the beginning, there are other cases, I think he would look at this verdict, if he were to accept it as I do, and order change. I'm convinced he's probably also an entirely decent person, and if he came to come to [sic] appreciate the effect

of the present product on the market killing people, as this jury says it did, some heads will roll. If Mr. Smilow isn't there any more, I'm sure he will have someone come to task. So, if I were plaintiff's counsel, I would see to it that the president of Beatrice understood what this jury said.

Additionally, if I were him I wouldn't have waited until today to place a copy of this verdict in the hands of Senators Dole and Kassebaum. Mr. Smilow may not know where Wichita is, or even Kansas, but my guess is he knows who they are. Congress is taking up strict liability and it's a [3527] subject of much controversy, and the likes of attorneys such as Mr. Michaud, I suppose, are the target, big verdicts and excessive damages. Already read in the New York—or the U.S. News a comment about this verdict, connotations that how unfortunate it is, how unreasonable it is, and you have got to do something. This is an opportunity for those two to come to grips with the problem and come to appreciate the view of a courtroom and our system.

If you will, I would suggest that both of them simply walk over to Secretary Heckler, the present Secretary of Health, Education and Welfare, who is the ultimate person responsible for FDA, and explain that verdict to her. I think she's the kind of person who would understand that. I think if that transpired, Mr. McCaghey, as earnest as you are with your appeal and your determination to have it, and you shall—I will assist you in any way—I'm convinced a FDA hearing would be taken up before your brief ever hits Denver.

I would suggest a hearing with the likes of Dr. Bergdoll, Osterholm, Chesney of the American College, Dr. Hanna. Let them come in and tell that panel what they know. Let's see how long it takes for somebody to say: Playtex, whether you like it or not, you're going to change your product. It's consistent with what this jury has said.

Now, with all of that said, there's one other option I want to extend to Playtex. I have studied Court's [3528] discretion in dealing with punitive damages. The remedies December [sic] are not clear. I'm sure Congress—and the Kansas legislature is studying it even today; their approach is to lop it off. Their approach is to say: Let the Judge set it. Legislatures or the Congress should never overlook the conscience of the community, a jury. Let them say. What is overlooked is the remedies.

If I accept this jury's verdict as a mandate for change, this verdict is not excessive in my view, so there is no real basis for me to mix in and change. On the other hand, as I see it—and there is no authority for it—I see the jury's verdict as quasi-criminal, and plaintiffs' verdict discussed that. As such, when I have people before me for punishment, mitigation is of interest to me. When someone says: I was wrong, I'm ready to change, I'm ready to do what is right, makes all the difference in the world.

As it would relate then to what I can do with regard to the punitive damage award, it's this, Mr. McCaghey: I'm going to set a hearing on April 29th at two o'clock in this courtroom. During this interim, I'm going to direct you to personally deliver to the president of Beatrice that jury verdict. If you want, take with you a transcript of these proceedings or my comments that I have just made. I want you to tell him that I find this verdict a mandate for change. He can read it and make his own judgment. You can tell him that [3529] in my view it's only the beginning. Other cases will follow. That his product as presently on the market is dangerously, defective. It needs change. If this gentleman agrees, he can appear in this Court or through his authorized representative on April the 29th at two o'clock and say so in open Court, and the trade-off for that is my assurance of substantial modification, if not complete remittitur.

The problems with any of this is the prerogatives of a plaintiff. They have a proprietary interest in that verdict. Kelly O'Gilvie isn't here, but I'm convinced he didn't file the suit to enrich himself. He filed this suit to vindicate his wife and punish your company. Seems to me a fair trade-off, if not a decent memorial for a very unnecessary death, that he were here to hear the president of Beatrice say: We are changing our ways.

The attorneys have a claim. As I said, Mr. Michaud is a target across this country. He's the epitomy of successful lawyers in malpractice and product liability and punitive damages. He may not agree. But I think I know Mr. Michaud well enough that he would. He's also a very responsible lawyer. He has drawn satisfaction in having used the Court to win, to demonstrate to this entire industry that this company is wrong. I kind of think Mr. Michaud as well would accept a trade-off to hear your company say: We are changing. I kind of think Mr. Michaud would accept that as [3530] satisfaction for having contributed in the courtroom to effect change in an industry.

With that said, Mr. McCaghey, unless you just refuse to comply, you can say so now. Your company has an opportunity here to get right, to act and to respond consistent with what I read this jury to say, and in concert with what I believe is my discretion in attempting to deal with that verdict in a reasonable way. Fair trade-off. All right?

MR. McCAGHEY: Your Honor, I would not presume to respond to your comments and your suggestion at this time. You can rest assured that it will be taken up with the appropriate parties. Mr. Coleman is here, general counsel of Playtex is here.

THE COURT: I think it's a fair proposition. I wouldn't expect you to say yes or no today. I will do this: I will stay execution through April 29th and, of course, the time for filing any notice of appeal would be stayed

until that time. You want to advise me to the contrary prior to that time, you simply need to say so. I think this is a fair proposition for everybody. It is a jury's verdict at work and I think it's fair and I think it would resolve once and for all what I perceive to be a correct verdict: That your product is defective and dangerous, it is killing people, and they ought to change. That's what the jury said.

APPENDIX H

STATUTES AND REGULATIONS INVOLVED

21 U.S.C. § 360k (1982)

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectivenes of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 C.F.R. § 801.430 (1987)

§ 801.430 User labeling for menstrual tampons.

(a) This section applies to scented or scented deodorized menstrual tampons as identified in § 884.5460 and unscented menstrual tampons as identified in § 884.5470 of this chapter.

(b) Available data show that toxic shock syndrome (TSS), a rare but serious and sometimes fatal disease, is associated with the use of menstural tampons. To protect the public and to minimize the serious adverse effects of TSS, menstrual tampons shall be labeled as set forth in paragraphs (c) and (d) of this section.

(c) If the information specified in paragraph (d) of this section is to be included as a package insert, the following alert statement shall appear prominently and legibly on the package label:

ATTENTION: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information.

(d) The consumer information required by this section shall appear prominently and legibly in a package insert or on the package, in terms understandable by the layperson and shall include statements concerning:

(1) (i) Warning signs of TSS, e.g., sudden fever (usually 102° or more) and vomiting, diarrhea, fainting or near fainting when standing up, dizziness, or a rash that looks like a sunburn;

(ii) What to do if these or other signs of TSS appear, including the need to remove the tampon at once and seek medical attention immediately;

(2) The risk of TSS to all women using tampons during their menstrual period, especially the reported higher risks to women under 30 years of age and teenage girls, the estimated incidence of TSS of 6 to 17 per 100,000 menstruating women and girls per year, and the risk of

death from contracting TSS;

(3) The advisability of using tampons with the minimum absorbency needed to control menstrual flow;

(4) Avoiding the risk of getting tampon-associated TSS by not using tampons, and possibly reducing the risk of getting TSS by alternating tampon use with sanitary napkin use during menstrual periods; and

(5) the need to seek medical attention before again using tampons if TSS warning signs have occurred in the past, or if women have any questions about TSS or tampon use.

(e) Any menstrual tampon dispensed by a vending machine is exempt from the requirements of this section.

(f) Any menstrual tampon that is not labeled as required by this section and that is initially introduced or initially delivered for introduction into commerce after December 20, 1982, is misbranded pursuant to sections 502(a) and 201(n) of the act.

(Secs. 201(n), 502, 701(a), 52 Stat. 1041 as amended, 1050-1051 as amended, 1055 (21 U.S.C. 321(n), 352, 371 (a))).

[47 FR 26989, June 22, 1982]

21 C.F.R. § 808.1 (1987)

PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

Subpart A—General Provisions

§ 808.1 Scope

(a) This part prescribes procedures for the submission, review, and approval of applications for exemption from Federal preemption of State and local requirements applicable to medical devices under section 521 of the act.

(b) Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

(c) Section 521(b) of the act contains a provision whereby the Commissioner of Food and Drugs may, upon application by a State or political subdivision, allow imposition of a requirement which is different from, or in addition to, any requirement applicable under the act to the device (and which is thereby preempted) by promulgating a regulation in accordance with this part exempting the State or local requirement from preemption. The granting of an exemption does not affect the applicability to the device of any requirements under the act. The Commissioner may promulgate an exemption regulation for the preempted requirement if he makes either of the following findings:

(1) That the requirement is more stringent than a requirement under the act applicable to the device; or

(2) That the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act.

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the aproval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podtiary, or any other of the healing arts or

allied medical sciences or related professions or occupations that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is pre-

empted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy Act of 1954 (42 U.S.C. 2011 note), as amended, the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263b et seq.)) and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

(e) It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any State or political subdivision whose requirements relating to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(f) The Federal requirement with respect to a device applies whether or not a corresponding State or local requirement is preempted or exempted from preemption. As a result, if a State or local requirement that the Food and Drug Administration has exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement applies to all circumstances not covered by the State or local requirement.